Appendix 4. Description of the consensus judgments for assigning a risk of bias in each domain by the ROBINS-I tool

Bias due to confounding	Butt AA 2021 Cohort	Dagan N 2021	Villar J 2023	Butt AA 2021 TND	Paixao ES 2022	Schrag SJ 2022
isk of bias judgement there potential for confound	Moderate ding of the effect of intervent Y	Moderate ion in this study?	Moderate	Low	Low	Low
id the authors use an approp	riate analysis method that co	ontrolled for all the importan	tconfounding domains?	·	,	
	Υ	Y	<u> </u>	У	<u>Y</u>	<u> </u>
vere confounding domains tr	N N	N	ne variables available in this s N	N N	N.	N
id the authors control for an	y post-intervention variables N	that could have been affecte N	d by theintervention?	N	[N	i N
observation: lias in selection of participan	articles to mitigate this cond However, our assessment ha rationale outlined in the [Wi medical care. This deliberate	ern, the variables used for so is led us to assign a "Low" ra HO article], which highlights	ature, there exists a potential uch adjustments are limited i sting to the following articles: a significant aspect of the tes ize unmeasured confounding	n number or lack validity and Butt AA 2021 TND, Paixao Est- negative design—namely,	reliability. 5 2022, and Schrag SJ 2022 the focus on a population v	. This decision is based on
isk of bias judgement	Low	Low	Serious	Low	Low	Low
Vas the selection of participa	nts into the study based on p N	articipant characteristics ob N	served after the start of the in	ntervention?	[Y
o start of follow-up and star	t of intervention coincide for PY	most participants? PY	PN	PN	[PN	PN
Vere adjustment techniques	used that are likely to correct					
	NA	NA NA	j N ssigning a low risk of bias to t	N N	j N	N N
ibservation: las in classification of interv	baseline characteristics and J 2023 received a classificati selection was based on post that while participant select	when the initiation of follow on of "Serious" risk due to th -intervention characteristics. ion occurs post-intervention,	-up and the commencement he lack of alignment between Regarding the TND articles, these designs have undergon	of intervention aligned for m the start of follow-up and th we deemed the risk of bias to	ost participants. In contras e initiation of intervention. b be "Low." This determina	t, the study conducted by \ Furthermore, participant tion stemmed from the fa
isk of bias judgement Vere intervention groups clea	Low orly defined?	Moderate	Low	Low	Low	Low
8 - 20 - 20 - 30 - 30 - 30 - 30 - 30 - 30	Y	N	<u> </u>	<u> </u>	Y	i
as the information used to	define intervention groups re PY	corded at the start of the int PY	ervention?	PY]Y	
ould the classification of inte			outcome or risk of the outcom			
	PN We decided to score this dor	PN	PN bias if the study described the	PN enterpention in terms of the	PN bype of vaccine used and t	PN PN
bservation: las due to deviations from in	was not the case in the stud		Sis in the stody described the	i intervention in terms of the	type or vaccine used and t	e desc daministered, uni
isk of bias judgement	Low	Low	Low	Low	Low	Low
Vere there deviations from the	ne intended intervention beyo N	ond what would be expected N	in usual practice?	N	l N	l N
bservation:	We decided to score this dor	main as having a low risk of	bias because any deviations f	rom the intended intervention	reflected usual practice.	
ias due to missing data isk of bias judgement	Low	Low	Low	Low	Moderate	Moderate
/ere outcome data available	for all, or nearly all, participa Y	ents?	J	[ļ N	[N
/ere participants excluded di	ue to missing data on interve		7	l N	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1 N
Vere participants excluded d	NI ue to missing data on other v	NI ariables needed for the analy	N	JN.	ļ N	N
	NI	PY	N e to the adequately comprehe	N ensive nature of the data, cou	N pled with the absence of a	N ny indications suggesting a
Observation:	notable divergence in the pro	oportion or ratio of missing p 1022 and Schrag SJ 2022 iten	participant data between the ns, we've opted for a "Moder	intervention groups.		
ias in measurement of outco isk of bias judgement		Moderate	Moderate	Low	Low	Low
	ave been influenced by know					
Vere outcome assessors awa	Y re of the intervention receive	Y ed by study participants?	[Y	<u>У</u>	. Y	Y
Vere the methods of outcom	PY e assessment comparable ac	PY ross intervention groups?	l PY	PY PY	PY	PY
Vere any systematic errors in	the measurement of the out	rome related to the interver	Y) Y	ļ Y) Y
and any agreement entrys in	N	N	<u> </u>	N at clinicians were likely awa	N n of the nations' allocation	N N
	groups in all instances. More Consequently, a "Moderate"	over, this awareness might rating was deemed appropr	e articles, we acknowledge th have been influenced by the p iate for cohort studies, consid	patients' COVID infection stat lering these inherent attribut	us, potentially introducing es. However, for test-nega	oias. ive design (TND) studies,
bservation: las in selection of the report			ng effectiveness [WHO refere		igned due to the outlined o	
lisk of bias judgement	Low	Low	Low	Low	Low	Low
s the reported effect estimat	N	N	nultiple outcome measureme N	nts within the outcome doma	nin? N] N
		in?				
. multiple analysis of the inte	ervention-outcome relationsh N	N	I N	N.	l N	, N
. multiple analysis of the inte . different subgroups? Observation:	N N	N N	N N bias because we have reporte	N	N	. L N

Table 2. Neonatal SARS-CoV-2 infect	ion			Table 3. Severe covid diseas	se	
	Carlsen EO 2022	Dan	ino D 2022		Guedalia J 2022	Villar J 2023
Blas due to confounding	1			Bias due to confounding		
Risk of bias judgement	Moderate the effect of interpretion in this stu		Critical	Risk of bias judgement	Moderate	Moderate
Is there potential for confounding of	Y	dyr.	PY	is there potential for confou	inding of the effect of interve	Y
Did the authors use an appropriate a	nalusis method that controlled for a	II the important or		Did the authors use an appr important confounding dom	opriate analysis method that	controlled for all the
	Y	a li anno anno	Υ		PY	Υ
Were confounding domains that wer this study?	e controlled for measured validly an	id reliably by the v	ariables available in	the variables available in th	that were controlled for mea is study?	
	l N	L	N		j N any post-intervention variable	N s that could have been
Did the authors control for any post-	intervention variables that could have	e been affected b	y the intervention?	affected by the intervention	? ! N	; N
	Given that all the included articles					
	exists a potential for confounding.					
	techniques were employed across variables used for such adjustment					
	and reliability. The decision to scor					
	on the use of the variable "Premat					
Observation:	being a post-intervention variable.			Observation:	We decided by consensus	
Bias in selection of participants into Risk of bias judgement	the study		Low	Bias in selection of participa Risk of bias judgement	ants into the study Low	Serior
Was the selection of participants int	o the study based on participant cha	racteristics observ		Was the selection of partici	pants into the study based or	participant characteristics
the intervention?				observed after the start of t		
	N N	1	Y		i N	Y
Do start of follow-up and start of int	ervention coincide for most participal	ants?	PN	Do start of follow-up and st	art of intervention coincide fo	or most participants?
	IN.			Were adjustment technique	s used that are likely to corre	
Were adjustment techniques used th	nat are likely to correct for the prese	nce of selection b	iases?	selection biases?		
	N Through collaborative agreement,	we determined the	N at assigning a low		NA NA	N
	risk of bias to this domain would b					
	selection relied on pre-intervention					
	initiation of follow-up and the com-	mencement of int	tervention aligned for			
01	most participants. In contrast, the			01	Marchael de d'houseaux	
Observation: Bias in classification of interventions	received a classification of "Seriou	s risk due to the i	ack or alignment	Observation: Bias in classification of inte	We decided by consensus	***************************************
Risk of bias judgement	Low		Low	Risk of bias judgement	Low	Low
Were intervention groups clearly def	ined?			Were intervention groups cl	early defined?	
	<u>Y</u>		Y		Y	<u> У</u>
Was the information used to define	intervention groups recorded at the	ctart of the intens	antion?	intervention?	o define intervention groups	recorded at the start of the
was the miorination used to define	Y	i i i i i i i i i i i i i i i i i i i	Y	intervention:	γ	Y
Could the classification of intervention	on status have been affected by know	wledge of the out	come or risk of the	Could the classification of in	ntervention status have been	affected by knowledge of the
outcome?	¥*************************************			outcome or risk of the outco		
	PN We decided to score this domain a	s having a low rist	PN k of bias if the study		PN	PN
	described the intervention in terms					
Observation:	dose administered.			Observation:	We decided by consensus	
Bias due to deviations from intended	l interventions Low		Low	Bias due to deviations from Risk of bias judgement	intended interventions	Low
Risk of bias judgement	Low		LOW	Were there deviations from	Low the intended intervention be	
Were there deviations from the inte	nded intervention beyond what wou	d be expected in a	usual practice?	expected in usual practice?		
	N We decided to score this domain a	- basilan a lass dal	N of blacksonson		<u> </u>	N N
Observation:	deviations from the intended inten			Observation:	We decided by consensus	
Bias due to missing data			***************************************	Bias due to missing data		×
Risk of bias judgement	Low		Low	Risk of bias judgement	Low	Low
Were outcome data available for all,	or nearly all, participants?			Were outcome data availab	le for all, or nearly all, partici	pants?
Were participants excluded due to m	issing data on intervention status?			Were participants excluded	due to missing data on inter-	vention status?
confounding domains?	·,			confounding domains?	· · · · · · · · · · · · · · · · · · ·	·
	l NI		NI	Were participants excluded	NI due to missing data on other	N variables needed for the
Were participants excluded due to m	issing data on other variables need	ed for the analysis	7	analysis?	and to import and an other	
	l N		NI		. NI	N
Observation:	of the data, coupled with the absen	ce of any indicatio	ns suggesting a notab	Observation:	We decided by consensus	******************************
Bias in measurement of outcomes				Bias in measurement of out	comes	
	Î .		Low	Risk of bias judgement		·
Risk of bias judgement	Low				Low have been influenced by kno	Moderate owledge of the intervention
	5	ntervention receiv	ed?		have been influenced by kno	Moderate owledge of the intervention
Risk of bias judgement Could the outcome measure have be	en influenced by knowledge of the i		ed? N	Could the outcome measure received?	have been influenced by kno	owledge of the intervention Y
Risk of bias judgement	en influenced by knowledge of the i N he intervention received by study pa		N	Could the outcome measure received?	have been influenced by kno N ware of the intervention recei	owledge of the intervention Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti	en influenced by knowledge of the i N Ne intervention received by study pa PY	rticipants?		Could the outcome measure received? Were outcome assessors av	have been influenced by kno N ware of the intervention recei	owledge of the intervention Y ived by study participants? PY
Risk of bias judgement Could the outcome measure have be	en influenced by knowledge of the i N Ne intervention received by study pa PY	rticipants?	N	Could the outcome measure received? Were outcome assessors av Were the methods of outco	N Nare of the intervention receipy Mare of the intervention receipy Mare assessment comparable Y	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses	en influenced by knowledge of the i N he intervention received by study pa PY ssment comparable across intervent Y	rticipants? ion groups?	PY Y	Could the outcome measure received? Were outcome assessors as were the methods of outcome assessors were the methods of outcomes.	have been influenced by kno N ware of the intervention recei PY me assessment comparable	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti	en influenced by knowledge of the i N he intervention received by study pa i pr sment comparable across intervent Y easurement of the outcome related	rticipants? ion groups?	N PY Y on received?	Could the outcome measure received? Were outcome assessors av Were the methods of outco	N Nare of the intervention receipy Mare of the intervention receipy Mare assessment comparable Y	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses	en influenced by knowledge of the i N he intervention received by study pa PY ssment comparable across intervent Y	rticipants? ion groups?	PY Y	Could the outcome measure received? Were outcome assessors as were the methods of outcome assessors were the methods of outcomes.	N Nare of the intervention receipy Mare of the intervention receipy Mare assessment comparable Y	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses	en influenced by knowledge of the i N he intervention received by study pa i pr sment comparable across intervent Y easurement of the outcome related	rticipants? ion groups?	N PY Y on received?	Could the outcome measure received? Were outcome assessors as were the methods of outcome assessors were the methods of outcomes.	N Nare of the intervention receipy Mare of the intervention receipy Mare assessment comparable Y	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti Were the methods of outcome asses Were any systematic errors in the measure and the methods of outcome asses	en influenced by knowledge of the i N In N In I	rticipants? ion groups?	N PY Y on received?	Could the outcome measure received? Were outcome assessors as were the methods of outco Were any systematic errors intervention received?	N Navare of the intervention receipry PY me assessment comparable Y n the measurement of the c	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses Were any systematic errors in the m Observation:	en influenced by knowledge of the i N he intervention received by study pa PY ssment comparable across intervent Y easurement of the outcome related N We decided by consensus	rticipants? ion groups?	N PY Y on received?	Could the outcome measure received? Were outcome assessors as were the methods of outcome any systematic errors intervention received? Observation:	N ware of the intervention receipy PY me assessment comparable Y in the measurement of the of	whedge of the intervention Y ved by study participants? PY across intervention groups? Y
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti Were the methods of outcome asses Were any systematic errors in the m Observation: Glass in selection of the reported res	en influenced by knowledge of the i N he intervention received by study pa PY ssment comparable across intervent Y easurement of the outcome related N We decided by consensus	rticipants? ion groups?	PY Y In received?	Could the outcome measure received? Were outcome assessors as were the methods of outco Were any systematic errors intervention received? Observation: Bits in selection of the repo	have been influenced by knot Navare of the intervention recei PY	wledge of the intervention Y ved by study participants? PY across intervention groups? Y succome related to the N
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of the ware of the methods of outcome assessors aware of the ware of the methods of outcome assessors aware of the ware any systematic errors in the methods of outcome assessors aware of the ware of the war	en influenced by knowledge of the i N he intervention received by study pa PY sment comparable across intervent Y easurement of the outcome related N We decided by consensus it Low to be selected, on the bases of the	ticipants? Ion groups? to the intervention	PY Y n received? NI	Could the outcome measure received? Were outcome assessors ave the methods of outcome any systematic errors intervention received? Observation: Biss in selection of the repeats of bias judgement is the reported effect estim is the reported effect estim.	N ware of the intervention receiper same assessment comparable in the measurement of the comparable in the comparable in the measurement of the comparable in t	wledge of the intervention Y ved by study participants? PY across intervention groups? Y outcome related to the N Low he bases of the result from
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of the outcome assessors aware of the methods of outcome assessors aware of the methods of outcome assessors and the methods of outcome assessors and the country of the coun	en influenced by knowledge of the i N In N In Intervention received by study pa PY Issment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low to be selected, on the bases of the domain?	ticipants? Ion groups? to the intervention	PY Y n received? NI	Could the outcome measure received? Were outcome assessors ave the methods of outcome any systematic errors intervention received? Observation: Biss in selection of the repeats of bias judgement is the reported effect estim is the reported effect estim.	N ware of the intervention recei PY me assessment comparable Y in the measurement of the c N We decided by consensus uted result Low and likely to be selected, on the	wledge of the intervention Y ved by study participants? PY across intervention groups? Y utcome related to the N Low he bases of the result from main?
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses Were any systematic errors in the m Observation: Dis in selection of the reported reselts of bias judgement Is the reported effect estimate likely measurements within the outcome of the reported of the reported of the reported reselts of the reported reselvent of th	en influenced by knowledge of the i N he intervention received by study pa PY sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low To be selected, on the bases of the domain? N	ticipants? Ion groups? to the intervention	PY Y n received? NI	Could the outcome measure received? Were outcome assessors av Were the methods of outco Were any systematic errors intervention received? Observation: Uses in selection of the report is the reported effect estim multiple outcome measurer	N ware of the intervention receipy of the intervention receipy ware of the intervention receipy of the intervention receipy of the intervention receipy of the intervention receipy of the intervention of the color of the intervention of the intervention of the color of the intervention of the int	wledge of the intervention Y ved by study participants? PY across intervention groups? Y utcome related to the N Low he bases of the result from main? N
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of the ware of the methods of outcome assessors aware of the ware of the methods of outcome assessors aware of the ware any systematic errors in the methods of outcome assessors aware of the ware of the war	en influenced by knowledge of the i N he intervention received by study pa PY sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low To be selected, on the bases of the domain? N	ticipants? Ion groups? to the intervention	N PY Y In received? Ni Low Low tiple outcome	Could the outcome measure received? Were outcome assessors av Were the methods of outco Were any systematic errors intervention received? Observation: Uses in selection of the report is the reported effect estim multiple outcome measurer	N ware of the intervention recei PY me assessment comparable Y in the measurement of the c N We decided by consensus uted result Low and likely to be selected, on the	wledge of the intervention Y ved by study participants? PY across intervention groups? Y vuctome related to the N Low he bases of the result from— main? Ship?
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses Were any systematic errors in the m Observation: Dias in selection of the reported reservisk of bias judgement Is the reported effect estimate likely measurements within the outcome of	en influenced by knowledge of the i N In intervention received by study pa PY Is sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low To be selected, on the bases of the domain? N N-on-outcome relationship?	ticipants? Ion groups? to the intervention	PY Y n received? NI	Could the outcome measure received? Were outcome assessors av Were the methods of outco Were any systematic errors intervention received? Observation: Uses in selection of the report is the reported effect estim multiple outcome measurer	N ware of the intervention receipy of the intervention receipy ware of the intervention receipy of the intervention receipy of the intervention receipy of the intervention receipy of the intervention of the color of the intervention of the intervention of the color of the intervention of the int	wledge of the intervention Y ved by study participants? PY across intervention groups? Y utcome related to the N Low he bases of the result from main? N
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti Were the methods of outcome asses Were any systematic errors in the m Observation: Dias in selection of the reported res Risk of bias judgement is the reported effect estimate likely measurements within the outcomemultiple analysis of the interventiodifferent subgroups?	en influenced by knowledge of the i N In N In Intervention received by study pa PY Is sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low to be selected, on the bases of the domain? N Non-outcome relationship? N N	ticipants? Ion groups? to the intervention	N PY Y In received? Ni Low Low tiple outcome	Could the outcome measure received? Were outcome assessors as were the methods of outco. Were any systematic errors intervention received? Observation: Blas in selection of the report is the reported effect estimmultiple outcome measure multiple analysis of the ir undifferent subgroups?	we decided by consensus We decided by consensus We decided by consensus total result Low ate likely to be selected, on the N N N N N	wledge of the intervention Y ved by study participants? PY across intervention groups? Y vuctome related to the N Low he bases of the result from— main? Ship?
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of t Were the methods of outcome asses Were any systematic errors in the m Observation: Dias in selection of the reported reselts of bias judgement Is the reported effect estimate likely measurements within the outcome of the measurements within the outcome of the intervention of the intervention. different subgroups? Observation:	en influenced by knowledge of the i N Ne intervention received by study pa PY sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low to be selected, on the bases of the domain? N n-outcome relationship? N	ticipants? Ion groups? to the intervention	N PY Y In received? NI Low Low Riple outcome N	Could the outcome measure received? Were outcome assessors av Were the methods of outco Were any systematic errors intervention received? Observation: Ulss in selection of the report of the reported effect estim multiple outcome measurer multiple analysis of the ir different subgroups? Observation:	N ware of the intervention receipy of the intervention receipy ware of the intervention receipy of the intervention receipy of the intervention receipy of the intervention receipy of the intervention of the color of the intervention of the color of the color of the intervention of the color	wiedge of the intervention Y veed by study participants? PY across intervention groups? Y utcome related to the N Low he bases of the result from main? N Nship?
Risk of bias judgement Could the outcome measure have be Were outcome assessors aware of ti Were the methods of outcome asses Were any systematic errors in the m Observation: Dias in selection of the reported res Risk of bias judgement is the reported effect estimate likely measurements within the outcome multiple analysis of the interventic different subgroups?	en influenced by knowledge of the i N In N In Intervention received by study pa PY Is sment comparable across intervent Y easurement of the outcome related N We decided by consensus It Low to be selected, on the bases of the domain? N Non-outcome relationship? N N	tticipants? ticipants? to the intervention result from mult	N PY Y In received? NI Low Low Riple outcome N	Could the outcome measure received? Were outcome assessors as were the methods of outco. Were any systematic errors intervention received? Observation: Blas in selection of the report is the reported effect estimmultiple outcome measure multiple analysis of the ir undifferent subgroups?	we decided by consensus We decided by consensus We decided by consensus total result Low ate likely to be selected, on the N N N N N	wiedge of the intervention Y veed by study participants? PY across intervention groups? Y utcome related to the N Low he bases of the result from main? N Nship?

Bias due to confounding	Dagan N 2021	Guedalia J 2022	Schrag SJ 2022
Risk of bias judgement	Moderate	Moderate	Moderate
Is there potential for confour	nding of the effect of interve	ntion in this study?	
	<u> </u>	PY	<u>Y</u>
Did the authors use an app	propriate analysis method th	at controlled for all the impor	tant confounding domains
	Y.	PY	Ÿ
	that were controlled for mea	sured validly and reliably by t	he variables available in th
study?	N	T N	N N
	·k		
Did the authors control for ar	ny post-intervention variable N	s that could have been affect	ed by theintervention?
the start of the intervention? Do start of follow-up and sta Were adjustment techniques Observation:	nts into the study I Low ants into the study based on N rt of intervention coincide for PY used that are likely to corre NA We decided by consensus	Y ct for the presence of selection NA We decided by consensus	PN PN on biases?
Risk of bias judgement	Moderate	Low	Low
Were intervention groups cle	arly defined?	T v	ν
		recorded at the start of the in	tervention?
confounding domains?		_F	
Could the classification of int	PY	<u> Y</u>	
		affected by knowledge of the	
	ervention status have been	affected by knowledge of the	outcome or risk of the
	PN PN	affected by knowledge of the	outcome or risk of the
outcome?			
outcome? Observation: Blas due to deviations from I	PN We decided by consensus intended interventions	PN We decided by consensus	PN
outcome? Observation: Blas due to deviations from Risk of bias judgement	PN We decided by consensus	PN PN	
outcome? Observation: Blas due to deviations from Risk of bias judgement	PN We decided by consensus intended interventions Low	PN We decided by consensus	PN
outcome? Observation: Blas due to deviations from Risk of blas Judgement	PN We decided by consensus intended interventions Low	PN We decided by consensus Low	PN
outcome? Observation: Blas due to deviations from likes of bias judgement Were there deviations from l	PN We decided by consensus intended interventions Low the intended intervention be	PN We decided by consensus Low yond what would be expected N	PN Low
outcome? Observation: Blas due to deviations from I Risk of bias judgement Were there deviations from I Observation:	PN We decided by consensus intended interventions Low the intended intervention be	PN We decided by consensus Low yond what would be expected	PN Low
outcome? Observation: Bias due to deviations from this of bias judgement Were there deviations from the observation: Observation: Bias due to missing data Risk of bias judgement	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low	PN We decided by consensus Low yond what would be expected N We decided by consensus Low	PN Low
outcome? Observation: Bias due to deviations from this of bias judgement Were there deviations from the observation: Observation: Bias due to missing data Risk of bias judgement	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, particle	PN We decided by consensus Low yond what would be expected N We decided by consensus Low	Low In usual practice? N
outcome? Observation: Bias due to deviations from this of bias judgement Were there deviations from the observation: Observation: Bias due to missing data Risk of bias judgement	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low	PN We decided by consensus Low yond what would be expected N We decided by consensus Low	PN Low i in usual practice? N
observation: Bias due to deviations from Risk of bias judgement Were there deviations from I Observation: Bias due to missing data Risk of bias judgement Were outcome data available	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, particity due to missing data on intervention intervention be	PN We decided by consensus Low yond what would be expected N We decided by consensus Low pants? Y	Low In usual practice? N
observation: Bias due to deviations from Risk of bias judgement Were there deviations from I Observation: Bias due to missing data Risk of bias judgement Were outcome data available	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, partici	PN We decided by consensus Low yond what would be expected N We decided by consensus Low pants? Y	Low In usual practice? N
outcome? Observation: Blas due to deviations from I Risk of bias judgement Were there deviations from I Observation: Blas due to missing data Risk of bias judgement Were outcome data available Were participants excluded o	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, particity due to missing data on intenning	PN We decided by consensus Low yond what would be expected N We decided by consensus Low pants? Y wention status? NI	Low I in usual practice? N Low N
outcome? Observation: Blas due to deviations from I Risk of bias judgement Were there deviations from I Observation: Blas due to missing data Risk of bias judgement Were outcome data available Were participants excluded o	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, particity due to missing data on intenning	PN We decided by consensus Low yond what would be expected N We decided by consensus Low pants? Y ention status?	Low I in usual practice? N Low N
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outcome? Observation: Blas due to deviations from I Risk of bias judgement Were there deviations from I Observation: Blas due to missing data Risk of bias judgement Were outcome data available Were participants excluded o	PN We decided by consensus intended interventions Low the intended intervention be N We decided by consensus Low e for all, or nearly all, particity the to missing data on intervention be to missing data on other for the same particity of the torus of the same particity of the torus of the same particity	PN We decided by consensus Low yond what would be expected N We decided by consensus Low pants? Y wention status? NI variables needed for the ana	Low I in usual practice? N Low N N
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	Fell DB (1) 2022	Goldshtein I 2022	Ibroci E 2022	Blakeway H 2021	Boelig RC 2022	Cao M 2022
ias due to confounding						
sk of bias judgement	Low	Moderate	Low	Serious	Low	Critical
there potential for confoundin	ng of the effect of intervention in t	his study?				······
d the authors use an appropria	te analysis method that controll	ed for all the important confou	inding domains?			······································
	Y	Y	Y	Y	Y	Y
ere confounding domains that	were controlled for measured va	lidly and reliably by the variab	les available in this study?			
	Y	N N	Y	NI ;	ΥΥ	N
id the authors control for any p	ost-intervention variables that c	ould have been affected by the	intervention?	NI I	N	PY
	Articles demonstrating a strong	alignment by employing valid.	and dependable covariates were			
			nethods, a "Moderate" classification			
			nent of "Serious" was attributed. 1			
	variables were employed for adju	istment purposes.		*************************		*************
as in selection of participants i				3		
isk of bias judgement	Low	Serious	Low	Low	Low	Serious
as the selection of participants	s into the study based on particip N	ant characteristics observed at	nter the start of the intervention?	N .	N	Y
o start of follow-up and start of	fintervention coincide for most p	articipants?				
	PY	PN	PY	PY	PY	PN
/ere adjustment techniques use	ed that are likely to correct for the	presence of selection biases?				
	NA NA	N N	NA NA	NA NA	NA NA	NI
			iting a domain with a low risk of b			
			follow-up and the initiation of int ollow-up and the initiation of int			
	mitigate this potential bias.	mere the commencement of i	mow-up and the initiation of int	ervention do not align, and the	authors have not implemented	corrective techniqu
bservation: las in classification of intervent						
isk of bias judgement	Low	Moderate	Low	Low	Low	Low
Vere intervention groups clearly	λλ.		<u> </u>			
	Υ	N	Y	Υ [Υ	Y
as the information used to defi	ine intervention groups recorded	at the start of the intervention	n?			
	Y	Y	Y	Y	Υ	Y
ould the classification of interv	ention status have been affected					
	PN	PN	PN I	PN .	PN	PN
69 101 N	we opted to assign a Low risk o	r bias rating to this domain ir i	the study provided a comprehens	ave description of the interventi	on, encompassing details abou	t the specific vaccine
Observation: Sias due to deviations from inte	- de distance de la company					
isk of bias judgement	Low	Low	Low	Low	Low	Low
	ntended intervention beyond wh					
	N	N	N	N	N	N
bservation:	We decided to score this domain	as having a low risk of bias be	cause any deviations from the int	ended intervention reflected us	ual practice.	
ias due to missing data						
isk of bias judgement	Low	Low	Low	Low	Low	Moderate
Vere outcome data available for	all, or nearly all, participants?		·p			
	<u>Y</u> i	Υ	<u> </u>	<u>Yi</u>	Y	PN
Vere participants excluded due	to missing data on intervention s	tatus? PY	PY		NI	N
Vere narticinants excluded due	to missing data on other variable		PT		INI	N
rere participants excluded due	N N	PY	PY	NI [NI	N
			adequately comprehensive natu			gesting a notable
			ta between the intervention grou			
bservation:	regarding the outcome missing o	lata.				
ias in measurement of outcom	47					
	G1		V			
isk of bias judgement	Low	Low	Low	Low	Low	Low
isk of bias judgement	Low e been influenced by knowledge	of the intervention received?				
isk of bias judgement ould the outcome measure hav	Low e been influenced by knowledge o PN	of the intervention received? PN	Low	Low PN	Lów PN	Low PN
isk of bias judgement ould the outcome measure hav	Low e been influenced by knowledge o PN If the intervention received by stu	of the intervention received? PN dy participants?	PN [PN i	PN	PN
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isk of bias judgement ould the outcome measure hav Vere outcome assessors aware o	Low e been influenced by knowledge o PN If the intervention received by stu	of the intervention received? PN dy participants? PY	PN [PN i	PN	PN
isk of bias judgement ould the outcome measure hav Vere outcome assessors aware o Vere the methods of outcome as	Low e been influenced by knowledge of PN f the intervention received by stu	of the intervention received? PN idy participants? PY ervention groups? Y	PN PY	PN PY	PN PY	PN PY
isk of bias judgement ould the outcome measure hav lere outcome assessors aware o lere the methods of outcome as lere any systematic errors in the	Low e been influenced by knowledge PN f the intervention received by stupy Seessement comparable across into Y e measurement of the outcome r N	of the intervention received? PN dy participants? PY ervention groups? Y elated to the intervention rece	PN PY Y ived?	PN PY Y	PN PY Y	PN PY Y
sk of bias judgement uild the outcome measure hav ere outcome assessors aware o ere the methods of outcome as ere any systematic errors in th	Low e been influenced by knowledge PN f the intervention received by stupy Seessement comparable across into Y e measurement of the outcome r N	of the intervention received? PN dy participants? PY ervention groups? Y elated to the intervention rece	PN PY Y	PN PY Y	PN PY Y	PN PY Y
sk of bias judgement uuld the outcome measure hav ere outcome assessors aware o ere the methods of outcome a ere any systematic errors in th oservation:	Low e been influenced by knowledge PN if the intervention received by stu PY ssessment comparable across int Y e measurement of the outcome re N We decided to score this domain	of the intervention received? PN dy participants? PY ervention groups? Y elated to the intervention rece	PN PY Y ived?	PN PY Y	PN PY Y	PN PY Y
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isk of bias judgement ould the outcome measure hav lere outcome assessors aware o lere the methods of outcome as lere any systematic errors in the leservation: leservation: leservation of the reported lisk of bias judgement the reported effect estimate lik multiple analysis of the interven	Low e been influenced by knowledge PN f the intervention received by stu PY ssessment comparable across inter Y e measurement of the outcome re N We decided to score this domain tresult Low kely to be selected, on the bases of N	of the intervention received? PN dy participants? PY ervention groups? Y slated to the intervention rece N as "Low" risk of bias because of	PN PY V Ived? N our safety events of interest are within the	PN PY Y Nell defined and we can considere	PN PY Y N Nt them as a hard outcomes unl	PN PY Y N ikely to be misinterp
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isk of bias judgement ould the outcome measure hav Vere outcome assessors aware o Vere the methods of outcome as Vere any systematic errors in the observation: ias in selection of the reported isk of bias judgement	Low e been influenced by knowledge PN f the intervention received by stu PY ssessment comparable across into Y e measurement of the outcome re N We decided to score this domain fresult Low kely to be selected, on the bases o N ention-outcome relationship? N	of the intervention received? PN dy participants? PY servention groups? Velated to the intervention rece N n as "Low" risk of bias because of Low f the result from multiple ou N N N	PN PY veed? N our safety events of interest are we Low tcome measurements within the	PN PY Y N ell defined and we can considere Low outcome domain? N N	PN PY Y N Not them as a hard outcomes unl Low N N N	PN PY Y N kely to be misinterp Low

Y analysis method t PN ere controlled for N c-intervention var N ticles demonstrat ilizing a limited su foderate" classific formation was absoere post-interven the study Low Low	abset of the crucial adj ation was assigned. In sent, an assessment of ition variables were er Serious I on participant chara	Y the important confour Y reliably by the variabl Y been affected by the N thy employing valid a ustment variables or cases where the mod "Serious" was attribu	Y les available in this st Y intervention? N sind dependable covar not adhering to soun el formulation or vari	Critical Y Y	tion methods, a
Y analysis method t PN recontrolled for N t-intervention var N ticles demonstrat ilizing a limited su doderate" classific formation was abs nere post-interven to the study to the study basec N tervention coincic PY hat are likely to co	revention in this study Y hat controlled for all it Y measured validly and Y iables that could have N ing a strong alignmeni beet of the crucial adj ation was assigned. In tent, an assessment of tion variables were er Serious I on participant chara Y	Y he important confour Y reliably by the variabl Y been affected by the N by employing valid a ustment variables or cases where the mod "Serious" was attribu	Y Inding domains? Y les available in this ste Y intervention? N Ind dependable covar not adhering to soun el formulation or vari	Y idy? Y PY iates were categorized at and reliable construct	Y Y N N ss*Low." For those ion methods, a
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PN re controlled for N L-intervention var N ticles demonstrat dilizing a limited su foderate" classific formation was abs ere post-interven o the study basec N tervention coincic PY hat are likely to co	Y measured validly and Y iables that could have N ing a strong alignment ibset of the crucial adj ation was assigned. In sent, an assessment of tion variables were er Serious d on participant chara Y	Y reliably by the variable Y been affected by the N t by employing valid a ustment variables or cases where the mod "Serious" was attribu	Y les available in this str Y intervention? N und dependable covar not adhering to soun el formulation or vari ted. The most stringe	y PY iates were categorized a d and reliable construct able selection lacked ac	N N as "Low." For those
re controlled for N N t-intervention var N ticles demonstrat ilizing a limited su toderate" classific formation was abs neire post-interven to the study Low to the study basee N tervention coincic PY hat are likely to co	Y iables that could have N N ing a strong alignmen ibset of the crucial adj ation was assigned. In sent, an assessment of tion variables were er Serious I on participant chara Y	Y been affected by the N t by employing valid a ustment variables or cases where the mod "Serious" was attribu	Y Intervention? N Intervention? N Ind dependable covar not adhering to soun el formulation or vari ted. The most stringe	y PY iates were categorized a d and reliable construct able selection lacked ac	N N as "Low." For those
N Lintervention var N ticles demonstrat dizing a limited su loderate" classific- formation was ab- sere post-interven the study Low to the study basee N Levention coincic PY hat are likely to co	Y iables that could have N N ing a strong alignmen ibset of the crucial adj ation was assigned. In sent, an assessment of tion variables were er Serious I on participant chara Y	Y been affected by the N t by employing valid a ustment variables or cases where the mod "Serious" was attribu	Y Intervention? N Intervention? N Ind dependable covar not adhering to soun el formulation or vari ted. The most stringe	PY iates were categorized a d and reliable construct able selection lacked ac	N as "Low." For those tion methods, a
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N ticles demonstrat tilizing a limited su toderate" classific formation was absere post-interven to the study basec N tervention coincic PY hat are likely to co	N ing a strong alignmen best of the crucial adj ation was assigned. In eent, an assessment of tion variables were er Serious d on participant chara Y	N t by employing valid a ustment variables or cases where the mod "Serious" was attribu	N and dependable covar not adhering to soun- el formulation or vari ted. The most stringe	iates were categorized a d and reliable construct able selection lacked ac	as "Low." For those tion methods, a
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N tervention coincid PY hat are likely to co	Y		Serious	Serious	Low
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hat are likely to co	de for most participan PN	ts? PN	DN	PN	PY
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THE RESERVE OF THE PARTY OF THE	N	N N	l N	N	NA NA
		J	J	ow risk of bias is warrar	
ection hinges on p	pre-intervention base	line characteristics, a	nd the synchronizatio	n between the onset of	follow-up and the
			U 1700 U U	, a study is designated	
			tion do not align, and	the authors have not in	nplemented correctiv
	ate this potential bias.				
15					
	Moderate	Low	Low	Low	Moderate
	N	T v	T v	v	N
					L
Y	Υ	Y	Y	γ	Y
ion status have be	een affected by knowle	edge of the outcome o	or risk of the outcome	?	
PN	PN	PN	PN PN	PN	PN
[1] 이 이 아이는 사람이 된 17 () ()					
		accine type and dosag	ge administered. If suc	h information was lack	ing, the rating was
			~~~~~		
A		Å	·Å	LOW	Low
N I				N	N
e decided to score		A	A		<del></del>
Moderate	Low	Low	Low	Low	Low
, or nearly all, par	ticipants?	·			Ç
NI I	Y	Y	Y	Y	j Y
	tervention status?	Y	Y		t
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		·	N	N	N
	ign a "Low" rating to t				J
tervention groups	. We decided a "Mode	rate" rating if there ar	re inadequate provisio	on of information regard	ding the outcome mis
ta.					
Low	Low	Low	Low	Low	Low
		*********	·····		Y
			i PN	PN	PN
		γ	Tov	pv	DV
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easurement of the	e outcome related to t	he intervention recei	ved?		
N	N	N	N N	N	N
			ur safety events of int	erest are well defined a	nd we can considered
em as a hard outco	omes unlikely to be m	isinterpreted			
sult		4			
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E C MAN CO TO THE C P AND CO TO THE C P AND CO TO THE C P AND CO TO THE CO.	e commencement chiniques to mitige is Moderate fined? N intervention group ion status have be PN e opted to assign a compassing detail tegorized as "Moderate or moderate or m	ecommencement of follow-up and the thiniques to mitigate this potential bias is Moderate Mode	ecommencement of follow-up and the initiation of interventiniques to mitigate this potential bias.    Moderate	commencement of follow-up and the initiation of intervention do not align, and thiniques to mitigate this potential bias.    Moderate	A commencement of follow-up and the initiation of intervention do not align, and the authors have not in thiniques to mitigate this potential bias.  Moderate Moderate Low Low Low Low Intervention?  N N N Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y Y

	ernal and offspring outcomes (c Ortqvist AK 2022 Sweden	ontinued) Perez-Machluf R 2022	Rottenstreich M 2022	Stock S 2022	Wainstock T 2021
ias due to confounding			į.		\$
isk of bias judgement	Moderate	Low	Serious	Moderate	Moderate
there potential for confoundir	ng of the effect of intervention in				·
	ΥΥ	Y	I Y	ү	1 Y
d the authors use an appropria	te analysis method that control	led for all the important confou	nding domains?		7
	Y	attaller om at mattaller ber de e constale	i Y	Υ	у у
ere contounding domains that	were controlled for measured v	alidly and reliably by the variab	les available in this study?	N	! N
d the south one control for one	N.		i NI		N
a the authors control for any p	ost-intervention variables that	could have been affected by the N	NI NI	N	i n
	Articles demonstrating a strong		and dependable covariates were ca		
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	현 프라이아 기사들에 가는 100 프라이트 100 프	able construction methods, a "Mod		
			evant information was absent, an a		
oservation:			ention variables were employed for		coroacea. The most stringer
as in selection of participants	***********	to mistances where post interv	entron variables were employed to	or adjustment purposes.	*************
sk of bias judgement	Low		Low	Low	
		serious		LUW	391095
as the selection of participant	into the study based on partici	pant characteristics observed an	ter the start of the intervention?	v	! v
atest offellow we and stort of	N.	1	i	<u> </u>	<u> </u>
start of follow-up and start of	fintervention coincide for most	PN	PY	PY	l PN
			Li	P1	.j
ere aujustment techniques use	ed that are likely to correct for th	re presence or selection diases?	I ala	KIA	T
	NA By manns of a collective consen	cur wa acceptained that attach	NA	NA as is wassanted when particin	i N
			ting a domain with a low risk of bi between the onset of follow-up an		
			petween the onset of follow-up an erious" in cases where the comme		
			erious" in cases where the comme chniques to mitigate this potentia		e initiation of intervention (
bservation:		not impremented corrective tec	ques co micigate this potentia	, vid3.	
as in classification of interven					
isk of bias judgement	Moderate	Low	Low	Low	Moderate
Vere intervention groups clearly	r		r		
	N N	Y	<u></u>	Y	<u> </u> N
as the information used to def	ne intervention groups recorde	d at the start of the intervention	1 <i>f</i> 		
	Y	Υ	iYi.	Y	<u>i</u> Y
ould the classification of interv		by knowledge of the outcome of	r		
	PN	PN	PN i	PN	PN PN
			he study provided a comprehensiv		
bservation:		and dosage administered. If suc	h information was lacking, the rati	ing was categorized as "Mode	rate."
ias due to deviations from inte	nded interventions				<u> </u>
isk of bias judgement	Low	Low	Low	Low	Low
Vere there deviations from the i	ntended intervention beyond w	hat would be expected in usual	practice?		
	N	N	N.	N	N N
bservation:	We decided to score this				
ias due to missing data					
isk of bias judgement	Low	Low	Moderate	Low	Low
	all, or nearly all, participants?				***************************************
	Y	Y	NI	Y	Y
Vere participants excluded due	to missing data on intervention	status?	~		~~
	NI	Υ	NI NI	NI	<u>!</u> ү
/ere participants excluded due	to missing data on other variabl	es needed for the analysis?			
	N N	N	NI NI	N	, NI
	We've chosen to assign a "Low"	rating to this section due to the	adequately comprehensive nature	e of the data, coupled with th	ne absence of any indication
			issing participant data between th		
bservation:		of information regarding the ou			
as in measurement of outcom					I
sk of bias judgement	Low	Low	Low	Low	Low
	e been influenced by knowledge		*		
	PN	PN	PN	PN	. PN
Jere nutrome assessors aware o	f the intervention received by st	udy participants?	·		
ere succome assessors awdie o	pv pv	pv	PY :	PY	PY
Vere the methods of outcome a	ssessment comparable across in	tervention groups?	i	E.E.	i
e. c. dire incompas of outcome d	V	y	γ	ν	l v
/ere any systematic errors in th	e measurement of the outcome	related to the intervention recei	ived?		.1
		N	N !	N	[ N
	M		Li	I defined and we can conside	red them as a hard outcome
	N We decided to score this doma	in as "I ow" risk of hise horsues o	a. Social cacino di iliterest ale Mei	. ac.med and we can conside	aca chemiasa naru outcome
	N We decided to score this doma	in as "Low" risk of bias because o			
bservation:	unlikely to be misinterpreted	in as "Low" risk of bias because o			
bservation: as in selection of the reported	unlikely to be misinterpreted result				
bservation: las in selection of the reported sk of bias judgement	unlikely to be misinterpreted result Low	in as "Low" risk of bias because o	Low	Low	Low
bservation: las in selection of the reported isk of bias judgement	unlikely to be misinterpreted result		Low	Low	Low
bservation: las in selection of the reported isk of bias judgement	unlikely to be misinterpreted result Low		Low	Low	Low
bservation: las in salection of the reported isk of bias judgement the reported effect estimate lii	unlikely to be misinterpreted I result Low cely to be selected, on the bases N	Low	·		
bservation: las in selection of the reported isk of bias judgement the reported effect estimate lii	unlikely to be misinterpreted I result Low cely to be selected, on the bases N	Low	·		
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bservation: las in selection of the reported isk of bias judgement	unlikely to be misinterpreted i result Low kely to be selected, on the bases N ention-outcome relationship?	Low	N I	N	N
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bservation: las in selection of the reported isk of bias judgement the reported effect estimate lil multiple analysis of the interv different subgroups?	unlikely to be misinterpreted I result Low kely to be selected, on the bases N ention-outcome relationship? N	Low N N	N	N N	N N