

Supplementary Table S1 Literature search strategies in Medline and Embase (date last searched: September 7, 2021)		
No.	Searches	Results
Medline		
1	Palivizumab/ or (synagis).ab,ti,kw	831
2	Hospitalization/OR Treatment outcome/OR Pneumonia/OR Bronchiolitis/OR Respiratory Syncytial Virus Infections/OR Anaphylaxis/OR Thrombocytopenia/OR Hypersensitivity/OR (safety or effectiveness or efficacy or hospitalization or hospital admission* or adverse event* or immunogenicity or mechanical ventilation or pneumonia or bronchiolitis or hypersensitivity).ab,ti,kw.	2,988,863
3	((hospitalized or hospitalization*) adj5 (rate or rates or incidence or prevalence or percent* or number* or epidemiology)).ab,ti.	26,753
4	2 OR 3	2,999,164
5	1 AND 4	787
6	limit 7 to (abstracts and Humans)	604
Embase		
1	Palivizumab/or (synagis).ab,ti,kw	3,084
2	Hospitalization/OR Treatment outcome/OR Pneumonia/OR Bronchiolitis/OR Respiratory Syncytial Virus Infection/OR Anaphylaxis/OR Thrombocytopenia/OR Hypersensitivity/OR Adverse event/OR Adverse drug reaction/OR (safety or effectiveness or efficacy or hospitalization or hospital admission* or immunogenicity or mechanical ventilation).ab,ti,kw	4,095,633
3	((hospitalized or hospitalization*) adj5 (rate or rates or incidence or prevalence or percent* or number* or epidemiology)).ab,ti.	44,927
4	2 OR 3	4,104,988
5	1 AND 4	2,088
6	limit 7 to (abstracts and humans)	1,646

Supplementary Table S2 Characteristics, key findings, and methodological quality assessment of clinical trials included in the systematic review (five studies)

Study	Country/study period	Type of population and number of patients	Palivizumab regimen	Key efficacy findings	Key safety findings	Methodological quality assessment
Phase III RCT Connor, 1998 IMPact-RSV trial ¹²	Canada, the United Kingdom, and the United States 1996–1997	Premature infants • Palivizumab: 506 • Placebo: 234 Infants with BPD • Palivizumab: 496 • Placebo: 266	Five doses of palivizumab 15 mg/kg every 30 d	Rate of RSV-related hospitalization Premature infants • Palivizumab: 1.8% • Placebo: 8.1% $p < 0.001$ 78% reduction in RSV-related hospitalizations ($p = 0.001$) Infants with BPD • Palivizumab: 7.9% • Placebo: 12.8% $p < 0.001$ 39% reduction in RSV-related hospitalizations ($p = 0.038$) RSV-related mortality Premature infants • Palivizumab: 0.2% • Placebo: 0% (p -value not provided)	All patients AEs • Palivizumab: 11% • Placebo: 10% No SAEs were reported	Low risk of bias
Carbonell-Estrany et al, 2010 ¹³	Multinational 2004–2006	Infants with BPD - Palivizumab: 723 - Motavizumab: 722	Five doses of palivizumab 15 mg/kg every 30 d	Rate of RSV-related hospitalization • Palivizumab: 3.9% • Motavizumab: 3.0%	Palivizumab: 86.0% experienced more than one AE Psychiatric AEs: 2.9% 15.3% developed more than one SAEs	Low risk of bias
Feltes et al, 2003 ¹⁴	Multinational 1998–2002	Infants with hs-CHD • Palivizumab: 639 • Placebo: 648	Five doses of palivizumab 15 mg/kg every 30 d	Rate of RSV-related hospitalization • Palivizumab: 5.3% • Placebo: 9.7% Relative reduction in RSV-related hospitalization of 45% (95% CI, 23–67) $p = 0.003$ Rate of ICU admission • Palivizumab: 38.2% • Placebo: 38.1% Mechanical ventilation • Palivizumab: 23.5% • Placebo: 22.2% RSV-related mortality • Palivizumab: 0.3% • Placebo: 0.6% (p -value not provided)	AEs • Palivizumab: 7.2% • Placebo: 6.9% $p = 0.914$ SAEs • Palivizumab: 0% • Placebo: 0.5%	Low risk of bias

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Supplementary Table S2 (Continued)

Study	Country/study period	Type of population and number of patients	Palivizumab regimen	Key efficacy findings	Key safety findings	Methodological quality assessment
Phase II/III RCT						
Turti et al, 2012 ¹⁵	Russia 2009–2010	100	NR	NR	AEs: 3.0%	Low risk of bias
Phase-IV nonrandomized trial						
Makari et al, 2014 ¹⁶	The United States 2005–2007	Premature infants (<35 WGA and age ≤6 mo or infants with BPD of prematurity and age ≤24 mo): 413	NR	NR	One patient (0.3%) developed immunogenicity	Low risk of bias

Abbreviations: AE, adverse event; BPD, bronchopulmonary dysplasia; CI, confidence interval; hs-CHD, hemodynamically significant congenital heart disease; NR, not reported; RSV, respiratory syncytial virus; SAE, serious adverse events; US, United States; WGA, weeks gestational age.

Supplementary Table S3 Characteristics, key findings, and methodological quality assessment of observational studies included in the systematic review (55 studies)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Ambispective cohort					
Abushahin et al, 2018 ¹⁷	Qatar (November 2009–March 2012)	All infants: 429 • Premature (≤ 35 Wga): 300 • BPD: 80 • - hs-CHD: 49	RSV-related hospitalization rate • 2009–2010: 2.1% • 2010–2011: 1.2% • 2011–2012: 1.6% RSV-related ICU admission 14.3%	NR	JBIC Checklist for Cohort Studies: 6
Chi et al, 2014 ¹⁸	Taiwan (July 2000–March 2013)	After matching: • Palivizumab ◦ All infants: 127 ◦ BPD: 100 ◦ CHD: 10 • No palivizumab ◦ All infants: 127 ◦ BPD: 101 ◦ CHD: 11	RSV-related hospitalization rate Premature, at 6 mo: • Palivizumab: 0.9% • No palivizumab: 10.4% $p = 0.007$ Premature, at 12 mo: • Palivizumab: 3.7% • No palivizumab: 16.0% $p = 0.005$ BPD patients, at 6 mo: • Palivizumab: 2.0% • No palivizumab: 9.9% $p = 0.039$ BPD patients, at 12 mo: • Palivizumab: 4.0% • No palivizumab: 16.8% $p = 0.006$ No RSV-related deaths were reported	AEs 6.4% Serious AEs 0.3%	JBIC Checklist for Cohort Studies: 8
Resch et al, 2006 ¹⁹	Austria (2001–2003)	All infants: 801 • BPD: 32 • hsCHD: 19	RSV-related hospitalization rate • Adequate palivizumab prophylaxis: 3.3% • Inadequate palivizumab prophylaxis: 8.1% $p = 0.07$ Inadequate prophylaxis defined as receiving only one injection	NR	Not applicable
Case-control study					
Viguria et al, 2021 ²⁰	Spain (2011–2019)	• RSV-positive: 35 • RSV-negative: 107	Effectiveness of palivizumab • Any dose of palivizumab: 82% (95% CI, 29–96), $p = 0.0102$ - Palivizumab dose in prior 30 d vs. none: 79% (95% CI, 16–96), $p = 0.0234$ Calculated as (1-OR)X100. Logistic regression analysis adjusted by age group (0–5, 6–11, 12–23 mo) and health care setting (outpatient or hospitalization)	NR	JBIC Checklist for Case-Control Studies: 8
Cross-sectional study					
de Souza et al, 2019 ²¹	Brazil (January 2016–June 2016)	hs-CHD: 104	RSV-related hospitalization rate 0%	NR	JBIC Checklist for Cross-Sectional Studies: 5
Bar-Yoseph et al, 2019 ²²	Israel (2007–2017)	All infants: 42 • Palivizumab: 27 • No palivizumab: 15	Long-term morbidity Similar rates of recurrent wheezing, coughing, nighttime wheezing, exercise-induced wheezing, stridor, and recurrent pneumonia Differences in dyspnea ($p = 0.056$): • Palivizumab: 52%	NR	JBIC Checklist for Cohort Studies: 5

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Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Kusuda et al, 2006 ²³	Japan (2002–2003)	All infants: 6,302 • Palivizumab: 2,806 • - No palivizumab: 3,496	<ul style="list-style-type: none"> No palivizumab: 20% Differences in snoring ($p = 0.016$): Palivizumab: 7% No palivizumab: 40% 	NR	JBI Checklist for Cross-Sectional Studies: 6
Prais et al, 2016 ²⁴	Israel (period not reported)	BPD: 63 • Palivizumab: 30 • No palivizumab: 33	<ul style="list-style-type: none"> RSV-related hospitalization rate Palivizumab: 6.7% No palivizumab: 57.6% $p = 0.033$ Parent-reported wheezing episodes During the first 2 years of life: Palivizumab: 26.7% No palivizumab: 69.7% $p = 0.008$ During the year preceding study enrollment: Palivizumab: 13.3% No palivizumab: 18.2% Not significant Upper respiratory tract infection, during the year preceding study enrollment: Palivizumab: 30.0% No palivizumab: 69.7% $p < 0.005$ 	NR	JBI Checklist for Cross-Sectional Studies: 6
Phase III/IV open label study					
Groothuis, 2001 ²⁵	Multinational (November 1998–March 1999)	565	No RSV-related deaths were reported	NR	Not applicable (Conference abstract)
Phase IV open label study					
Groothuis, 2003 ²⁶	Europe, Saudi Arabia (2000–2001)	Premature: 285	<ul style="list-style-type: none"> RSV-related hospitalization rate 2.1% RSV-related ICU admission 33.3% Mechanical ventilation 33.3% 	<ul style="list-style-type: none"> AEs 2.1% Serious AEs 1.4% 	JBI Checklist for Case Series: 6
Prospective cohort study					
Paes et al, 2012 ²⁷	Canada (October 2006–May 2011)	All infants: 6,654 • ≤ 32 WGA: 5,183 • 33–35 WGA: 1,471	<ul style="list-style-type: none"> RSV-related hospitalization rate 1.5% RSV-related ICU admission ≤ 32 WGA: 25.8% 33–35 WGA: 27.8% $p = 1.000$ Mechanical ventilation 13.7% 	NR	JBI Checklist for Cohort Studies: 6
Li et al, 2017 ²⁸	Canada (2005–2015)	hs-CHD: 1,909	RSV-related hospitalization rate	NR	JBI Checklist for Cohort Studies: 8

Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Yoshihara et al, 2013 ²⁹	Japan (April 2008–December 2008)	All infants: 444 • Palivizumab: 349 • No palivizumab: 95	RSV-related ICU admission • First year of life: 33.3% • Second year of life: 42.9% $p=0.677$ Mechanical ventilation • First year of life: 25.9% • Second year of life: 0% $p=0.300$	NR	JBI Checklist for Cohort Studies: 8
Han et al, 2015 ³⁰	South Korea (September 2007–April 2008)	BPD: 90	Physician-diagnosed recurrent wheezing 6.4% RR: 0.34 (95% CI, 0.19–0.60)	NR	JBI Checklist for Case Series: 8
Lacaze-Masmonteil et al, 2002 ³¹	France (September 1999–January 2000)	All infants: 516 • BPD: 400	RSV-related hospitalization rate 8.9% Mechanical ventilation 25.0% RSV-related mortality 1.1% (among infants with BPD and history of premature birth [≤ 35 WGA] and low birth weight [$\leq 1,500$ g])	NR	JBI Checklist for Case Series: 5
Charkaluk et al, 2021 ³²	France (April 2011–December 2011)	2,571	RSV-related hospitalization rate 9.0% No RSV-related deaths were reported Oxygen requirement Adjusted OR (95% CI) (ref: No palivizumab): • Incomplete treatment: 1.9 (0.5–6.6) • Complete treatment: 1.3 (0.5–3.4) Multivariate model adjusted for GA and factors associated with the outcome with $p < 0.20$ on univariate analysis Complete treatment: at least one dose for each month of RSV exposure in the community, up to five doses	NR	JBI Checklist for Cohort Studies: 8
Manzoni et al, 2017 ³³	Canada, Italy (2001–2014)	Premature: 9,093 • BPD: 1,199 • hs-CHD: 1,438	RSV-related hospitalization rate • BPD: 4.8% • hs-CHD: 4.1% RSV-related ICU admission • Premature: 16.6% • BPD: 7.0% • hs-CHD: 23.7% Mechanical ventilation • Premature: 13.7% • BPD: 7.0% • hs-CHD: 22.0%	NR	JBI Checklist for Cohort Studies: 7
Amitai et al, 2020 ³⁴	Israel (period not reported)	BPD: 46 • Palivizumab: 17 • No palivizumab: 29	Lung function parameters No statistically significant differences were observed between palivizumab and nonpalivizumab groups in adolescents aged 13–18 years who were born at < 29 WGA	NR	JBI Checklist for Cohort Studies: 6
Athiraman and Agarwal, 2012 ³⁵	The United Kingdom (period not reported)	BPD: 229 • Palivizumab: 166	RSV-related hospitalization rate 8.5%	NR	Not applicable (Conference abstract)
Soraiz et al, 2017 ³⁶			No RSV-related deaths were reported	NR	

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Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Oh et al, 2002 ³⁷	Argentina (2014–2016)	<ul style="list-style-type: none"> hs-CHD: 103 Historical cohort (i.e., did not receive treatment): 50 Palivizumab group: 53 	<ul style="list-style-type: none"> RSV-related hospitalization rate Premature: 1.2% BPD: 2.9% 	NR	Not applicable (Conference abstract)
Mochizuki et al, 2017 ³⁸	Canada (September 1999–May 2000)	<ul style="list-style-type: none"> All infants: 480 Premature: 345 BPD: 40 	<ul style="list-style-type: none"> Physician-diagnosed recurrent wheezing: 12.8% Atopic asthma: 15.3%, No significant risk reduction associated with the use of palivizumab 	NR	<ul style="list-style-type: none"> Physician-diagnosed recurrent wheezing: 12.8% Atopic asthma: 15.3%, No significant risk reduction associated with the use of palivizumab
Parnes et al, 2003 ³⁹	Japan (2007–2008)	<ul style="list-style-type: none"> All infants: 444 based on the analysis: ITT: 440 Palivizumab (at least 3 doses): 345 No palivizumab: 95 Per protocol: 328 Palivizumab (at least 3 doses): 249 No palivizumab: 79 Atopic asthma subpopulation: 268 Palivizumab (at least 3 doses): 202 No palivizumab: 66 	<ul style="list-style-type: none"> RSV-related hospitalization rate < 32 WGA: 986 32–35 WGA: 957 BPD: 500 CHD: 102 	NR	<ul style="list-style-type: none"> RSV-related hospitalization rate < 32 WGA: 4.5% 32–35 WGA: 1.6% BPD: 5.8% CHD: 4.3%
Simoes et al, 2007 ⁴⁰	The United States (September 2000–March 2001)	<ul style="list-style-type: none"> Palivizumab: 191 No palivizumab: 230 RSV hospitalized: 76 No RSV hospitalization: 154 	<ul style="list-style-type: none"> Physician-diagnosed recurrent wheezing: 7.9% Significant risk reduction associated with the use of palivizumab: RR: 0.49 (95% CI, 0.27–0.88) Caregiver-reported recurrent wheezing: 13.1% Significant risk reduction associated with the use of palivizumab: RR: 0.51 (95% CI, 0.33–0.78) 	NR	<ul style="list-style-type: none"> Physician-diagnosed recurrent wheezing: 7.9% Significant risk reduction associated with the use of palivizumab: RR: 0.49 (95% CI, 0.27–0.88) Caregiver-reported recurrent wheezing: 13.1% Significant risk reduction associated with the use of palivizumab: RR: 0.51 (95% CI, 0.33–0.78)
Paes et al, 2012 ⁴¹	Canada (October 2006–May 2010)	<ul style="list-style-type: none"> Premature infants: 4,880 	<ul style="list-style-type: none"> RSV-related hospitalization rate 1.3% (95% CI, 1.04–1.68) RSV-related ICU admission: 29.4% Mechanical ventilation: 7.8% 	NR	<ul style="list-style-type: none"> RSV-related hospitalization rate 1.3% (95% CI, 1.04–1.68) RSV-related ICU admission: 29.4% Mechanical ventilation: 7.8%
Oncel et al, 2013 ⁴²	Turkey (October 2011–March 2012)	<ul style="list-style-type: none"> 252 	<ul style="list-style-type: none"> RSV-related hospitalization rate 2.4% 	NR	<ul style="list-style-type: none"> RSV-related hospitalization rate 2.4%
SUNRISE Study (NCT02282982) ⁴³	Russia (Oct 2014–May 2015)	<ul style="list-style-type: none"> 359 	<ul style="list-style-type: none"> RSV-related hospitalization rate 0.3% No RSV-related deaths were reported 	NR	<ul style="list-style-type: none"> RSV-related hospitalization rate 0.3% No RSV-related deaths were reported
Retrospective cohort study					
Winterstein et al, 2011 ⁴⁴	The United States (1999–2004)	<ul style="list-style-type: none"> 21,825 	<ul style="list-style-type: none"> RSV-related hospitalization incidence rate 2.83 per 100 patient-seasons HR (ref. no palivizumab) (95% CI): Infants 0–1 years: 0.51 (0.38–0.68) Infants > 1–2 years: 0.88 (0.52–1.33) 	NR	<ul style="list-style-type: none"> RSV-related hospitalization incidence rate 2.83 per 100 patient-seasons HR (ref. no palivizumab) (95% CI): Infants 0–1 years: 0.51 (0.38–0.68) Infants > 1–2 years: 0.88 (0.52–1.33)

Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Buckley et al, 2010 ⁴⁵	The United States (2005–2008)	629	<ul style="list-style-type: none"> RSV-related hospitalization rate 6.4% 	NR	<ul style="list-style-type: none"> JBIC Checklist for Cohort Studies: 7
Elmasoudi et al, 2015 ⁴⁶	Qatar (2010–2013)	781	<ul style="list-style-type: none"> RSV-related hospitalization rate 5.4% in the first 16 mo of life RSV-related hospitalization incidence rate 5.31 per 100 person-years (95% CI, 3.90–5.9) 	AEs 7%	Not applicable
Sorrentino and Powers 2000 ⁴⁷	The United States (September 1998–May 1999)	<ul style="list-style-type: none"> All infants: 1,839 Premature: 1,604 BPD: 403 CHD: 40 	<ul style="list-style-type: none"> RSV-related hospitalization rate ≤35 WGA: 2.2 < 28 WGA: 3.4% 28–31 WGA: 2.0% 32–35 WGA: 1.4% ≤35 WGA without BPD: 2.1% BPD: 4.0% 	NR	<ul style="list-style-type: none"> JBIC Checklist for Case Series: 5
Chiu et al, 2018 ⁴⁸	Taiwan (July 2013–December 2015)	<ul style="list-style-type: none"> After matching by propensity score: <ul style="list-style-type: none"> Palivizumab: 705 ○ cyanotic hs-CHD: 311 ○ No palivizumab: 705 ○ cyanotic hs-CHD: 306 	<ul style="list-style-type: none"> RSV-related hospitalization incidence rate (Per 1,000 person-days [95% CI]): All patients Palivizumab: 0.076 (0.048–0.121) No palivizumab: 0.145 (0.104–0.203) $p < 0.05$ Cyanotic hs-CHD: <ul style="list-style-type: none"> Palivizumab: 0.093 (95% CI, 0.053–0.165) No palivizumab: 0.138 (95% CI, 0.087–0.219) $p = 0.287$ Cyanotic hs-CHD: <ul style="list-style-type: none"> Palivizumab: 0.056 (95% CI, 0.025–0.124) No palivizumab: 0.155 (95% CI, 0.095–0.252) $p = 0.028$ RR (ref: no palivizumab) (95% CI): 0.514 (0.283–0.934) Acyanotic hs-CHD: 0.649 (0.293–1.439) Cyanotic hs-CHD: 0.350 (0.137–0.895) RSV-related ICU admission (per 1,000 person-days [95% CI]): All patients Palivizumab: 0.030 (95% CI, 0.014–0.062) No palivizumab: 0.064 (95% CI, 0.039–0.106) RR: 0.426 (95% CI, 0.167–1.083) Not statistically significant Acyanotic hs-CHD: <ul style="list-style-type: none"> Palivizumab: 0.023 (95% CI, 0.05–0.072) No palivizumab: 0.061 (95% CI, 0.031–0.123) RR: 0.348 (95% CI, 0.103–1.176) Not statistically significant Cyanotic hs-CHD: <ul style="list-style-type: none"> Palivizumab: 0.037 (95% CI, 0.014–0.099) No palivizumab: 0.068 (95% CI, 0.032–0.142) RR: 0.528 (95% CI, 0.157–1.777) Not statistically significant 	NR	<ul style="list-style-type: none"> JBIC Checklist for Cohort Studies: 8
Blake et al, 2017 ⁴⁹	The United States (October 2012–March 2016)	<ul style="list-style-type: none"> Pre-2014 AAP: 98 Post-2014 AAP: 75 	<ul style="list-style-type: none"> RSV-related hospitalization rate Palivizumab: 1.6% No palivizumab: 2.8% 	NR	<ul style="list-style-type: none"> JBIC Checklist for Cohort Studies: 5

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Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Wang et al, 2017 ⁵⁰	Canada (2005–2015)	BPD: <ul style="list-style-type: none"> • First year: 847 • Second year: 450 	<ul style="list-style-type: none"> • RSV-related hospitalization rate • First year: 2.3% • Second year: 3.9% • RSV-related ICU admission • First year: 22.2% • Second year: 26.7% • $p > 0.999$ • Mechanical Ventilation • First year: 16.7% • Second year: 0 • $p = 0.233$ 	NR	JBI Checklist for Cohort Studies: 7
Lee et al, 2010 ⁵¹	The United States (period not reported)	All infants: 71 <ul style="list-style-type: none"> • BPD: 9 	<ul style="list-style-type: none"> • RSV-related hospitalization rate • 1.4% • Wheezing episodes: • 56.3% over a follow-up period of 11 years 	NR	Not applicable (Conference abstract)
Yeo et al, 2021 ⁵²	Singapore (August 2012–July 2017)	All infants: 415 <ul style="list-style-type: none"> • Palivizumab: 109 • No palivizumab: 306 	<ul style="list-style-type: none"> • RSV-related hospitalization rate • In the 6 mo after discharge: • Palivizumab: 0.9% • No palivizumab: 7.2% • $p = 0.01$, absolute reduction = 6.3% • In the 12 mo after discharge: • Palivizumab: 2.8% • No palivizumab: 10.5% • $p = 0.02$ • RSV-related hospitalization incidence rate • Over 0–6 mo after discharge: • Palivizumab: 18.3 • No palivizumab: 143.9 • $p = 0.01$ • Over the 7–9 mo after discharge: • Palivizumab: 0 • No palivizumab: 92.7 • $p = 0.25$ • Over the 10–12 mo after discharge: • Palivizumab: 81.6 • No palivizumab: 41.8 • $p = 0.75$ • At 6 mo postdischarge: • Effectiveness of palivizumab = 90% (95% CI, 10–99) • Adjusted OR = 0.1 (95%CI, 0.01–0.9) • From 7–12 mo postdischarge: • Effectiveness of palivizumab = 50% • Adjusted OR = 0.5 (95% CI, 0.1–3.0) • Effectiveness calculated as (1-OR)X100 • RSV-related ICU admission • Palivizumab: 0 • No palivizumab: 15.6% 	NR	JBI Checklist for Cohort Studies: 9
Diehl et al, 2010 ⁵³			<ul style="list-style-type: none"> • RSV-related hospitalization rate • All infants: 0.8% 	NR	JBI Checklist for Cohort Studies: 7

Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Quek et al, 2015 ⁵⁴	The United States (October 2006–April 2007) Singapore (December 2011–December 2013)	All infants: 245 • Compliant: n = 73 • Noncompliant: n = 172 BPD: 57	<ul style="list-style-type: none"> Compliant: 0% Noncompliant: 1.2% p = 1.000 RSV-related hospitalization rate Among patients that completed five doses of palivizumab: 6.3% Historical controls: 13.3% p < 0.05 RSV-related ICU admission: 33.3% Mechanical ventilation: 33.3% 	NR	Not applicable (Conference abstract)
Chang et al, 2010 ⁵⁵	South Korea (September 2004–March 2009)	BPD • Palivizumab: 75 • No palivizumab: 53	<ul style="list-style-type: none"> RSV-related hospitalization rate No palivizumab: 22.6% Palivizumab: 4.0% p < 0.001 RSV-related ICU admission No palivizumab: 25.0% Palivizumab: 33.3% p = 0.871 Mechanical Ventilation No prophylaxis: 25.0% Palivizumab: 33.3% p = 0.871 RSV-related death No prophylaxis: 1.9% Palivizumab: 0% 	AEs 4.0%	JBI Checklist for Cohort Studies: 7
Lee et al, 2018 ⁵⁶	China (Hong-Kong; 2010–2014)	All patients: 135 • Palivizumab: 40 • No palivizumab: 95 BPD • Palivizumab: 37 • No palivizumab: 28 Infants born < 27 WGA • Palivizumab: 23 • No palivizumab: 29	<ul style="list-style-type: none"> RSV-related hospitalization rate All patients: Palivizumab: 5.0% No palivizumab: 15.8% p = 0.096 Palivizumab with BPD: 5.4% No palivizumab with BPD: 21.4% Infants born < 27 WGA: Palivizumab: 8.7% No palivizumab: 33.3% p = 0.046 Palivizumab with BPD: 9.1% No palivizumab with BPD: 35.7% RSV-related ICU admission All patients: Palivizumab: 50.0% No palivizumab: 40.0% Palivizumab with BPD: 50.0% No palivizumab with BPD: 50.0% Infants born < 27 WGA: Palivizumab: 50.0% No palivizumab with BPD: 44.4% Palivizumab with BPD: 50.0% 	NR	JBI Checklist for Cohort Studies: 6

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Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Taylor and Baker, 2021 ⁵⁷	Canada	All infants: 423 • Palivizumab: 87 • No Palivizumab: 336	<ul style="list-style-type: none"> • No palivizumab with BPD: 60.0% • No RSV-related deaths were reported • RSV-related hospitalization rate • Within 4 wk of the previous dose: 66.7% • > 6 wk after third and final dose: 33.3% • RSV-related ICU admission • Palivizumab: 66.7% • No palivizumab: 10% • Mechanical Ventilation • Palivizumab: 33.3% • No palivizumab: 0% • No RSV-related deaths were reported 	NR	JBIC Checklist for Cohort Studies: 5
Krilov et al, 2014 ⁵⁸	The United States (2003–2009)	All infants: 8,443 • < 33 WGA: 1,433 • 33–34 WGA: 3,182 • BPD: 1,242 • - hs-CHD: 801	<ul style="list-style-type: none"> • RSV-related hospitalization rate • Fully prophylaxed: 7.9% • Partially prophylaxed: 11.7% • $p < 0.001$ • RSV-related hospitalization incidence rate • Fully prophylaxed: 10.0 • Partially prophylaxed: 14.5 • $p < 0.001$ 	NR	JBIC Checklist for Cohort Studies: 8
Mitchell et al, 2014 ⁵⁹	Canada (2005–2013)	All infants: 13,624 • hs-CHD: 1,758	<ul style="list-style-type: none"> • HR of RSV-related hospitalization • Adjusted HR (ref: premature only group): • hs-CHD: = 1.63 (95% CI, 1.09–2.439) • Adjusted for risk factors: living with siblings, residing with ≥ one smoker in household, family history of atopy, and multiple birth status 	NR	Not applicable (Conference abstract)
Mitchell et al, 2015 ⁶⁰	Canada (2005–2014)	12,137	<ul style="list-style-type: none"> • RSV-related hospitalization • HR (ref: 31–32 WGA) (95% CI): • ≤ 26 WGA: 4.2 (2.3–7.8) • 27–28 WGA: 2.3 (1.2–4.1) • 29–30 WGA: 1.8 (1.0–3.0) 	NR	Not applicable (Conference abstract)
Resch et al, 2017 ⁶¹	Austria (2004–2012)	All infants: 789 • Palivizumab: 262 • No palivizumab: 527	<ul style="list-style-type: none"> • RSV-related hospitalization rate: • Palivizumab: 3.1% • No palivizumab: 5.9% • $p = 0.042$ • OR (ref: no palivizumab): 0.504 (95% CI, 0.259–0.981) • Corresponding to a 50% relative risk reduction • RSV-related ICU admission • Palivizumab: 29% • No palivizumab: 23% • No statistical difference • Mechanical Ventilation • Palivizumab: 14% • No palivizumab: 19% • No statistical difference 	NR	JBIC Checklist for Cohort Studies: 6
Fang and Wang 2018 ⁶²	Taiwan (1999–2015)	BPD: 535	<ul style="list-style-type: none"> • Association between prophylactic palivizumab and later asthma development: 	NR	Not applicable (Conference abstract)

Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Chadha et al, 2012 ⁶³	The United States (November 2004–March 2009)	All infants: 1,965 • <29 WGA: 983 • 29–31 WGA: 973	<ul style="list-style-type: none"> OR = 1.473 (95% CI, 0.962–2.255) p = 0.075 RSV-related hospitalization incidence rate (Range per 1,000 patient-years): < 29 WGA: 72–132 29–31 WGA: 24–108 	NR	JBI Checklist for Cohort Studies: 5
Paes et al, 2019 ⁶⁴	Canada (2005–2017)	20,246	<ul style="list-style-type: none"> RSV-related hospitalization rate 1.3% RSV-related ICU admission 28.6% Requirement for intubation: Among RSV hospitalizations: 11.7% Among patients receiving palivizumab for standard indication: 0.18% 	NR	JBI Checklist for Cohort Studies: 9
Lavoie et al, 2019 ⁶⁵	Canada (November 2012–April 2016)	CHD: 325	<ul style="list-style-type: none"> RSV-related hospitalization rate 5.2% 	NR	Not applicable
Paes et al, 2013 ⁶⁶	Canada (2005–2012)	<ul style="list-style-type: none"> Premature: 8,751 BPD: 1,048 hs-CHD: 1,414 	<ul style="list-style-type: none"> RSV-related hospitalization rate 1.89% (n = 165) Premature: 1.36% BPD: 1.64% hs-CHD: 2.05% p < 0.0005 	NR	JBI Checklist for Cohort Studies: 7
Bonnet et al, 2011 ⁶⁷	10 countries of the European Union Period not reported	<ul style="list-style-type: none"> hs-CHD: 2,018 Cases: 1,009 Controls: 1,009 	<ul style="list-style-type: none"> NR 	<ul style="list-style-type: none"> Palivizumab users (cases) vs. controls SAEs of infection OR: 0.95 SAEs of arrhythmia OR: 1.64 Cumulative incidence of any primary SAE OR: 0.96 	Not applicable (Conference abstract)
Kim et al, 2016 ⁶⁸	South Korea (Oct 2009–March 2015)	hs-CHD: 466	<ul style="list-style-type: none"> RSV-related hospitalization rate 12.2% RSV-related ICU admission 24.6% Mechanical Ventilation 8.8% 	NR	JBI Checklist for Case Series: 8
Lin et al, 2019 ⁶⁹	Taiwan (2008–2013)	All infants: 2,096 • Palivizumab: 1,274 • No palivizumab: 822 BPD • Palivizumab: 243 • No palivizumab: 183	<ul style="list-style-type: none"> RSV-related ICU admission Premature Palivizumab: 8.3% No palivizumab: 9.1% BPD Palivizumab: 0% No palivizumab: 68.8% Mechanical Ventilation Premature 	NR	JBI Checklist for Cohort Studies: 6

(Continued)

Supplementary Table S3 (Continued)

Study	Country/study period	Type of population and number of patients	Key effectiveness findings	Key safety findings	Methodological quality score
Claydon et al, 2019 ⁷⁰	Canada (2012–2016)	hs-CHD: 325	<ul style="list-style-type: none"> • Palivizumab: 8.3% • No palivizumab: 6.8% • BPD • Palivizumab: 0% • No palivizumab: 43.8% • RSV-related hospitalization incidence rate • 4.2 per 100 season-approvals (95% CI, 2.5–6.6) • No RSV-related deaths were reported 	NR	JBI Checklist for Case Series: 7
Pedraz et al, 2003 ⁷¹	Spain (1998–2002)	Premature with or without BPD <ul style="list-style-type: none"> • Palivizumab: 1,919 • No palivizumab: 1,583 	<ul style="list-style-type: none"> • RSV-related hospitalization rate • Mean over two RSV seasons: • Palivizumab (2000–2001, 2001–2002): 3.95% • No palivizumab (1998–1999, 1999–2000): 13.3% • Extremely premature infants (≤ 28 WGA) ($p < 0.0001$): • Palivizumab: 5.4% • No palivizumab: 13.0% • Infants with BPD ($p < 0.007$): • Palivizumab: 5.5% • No palivizumab: 19.7% 	NR	JBI Checklist for Cohort Studies: 8

Abbreviations: AAP, American Academy of Pediatrics; AE, adverse event; BPD, bronchopulmonary dysplasia. CI, confidence interval; hs-CHD, hemodynamically significant congenital heart disease; JBI, Joanna Briggs Institute; NR, not reported; RSV, respiratory syncytial virus; SAE, serious adverse events; WGA, weeks gestational age.