

THE LANCET

Global Health

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed.
We post it as supplied by the authors.

Supplement to: Taylor MM, Kobeissi L, Kim C, et al. Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action. *Lancet Glob Health* 2020; published online Dec 16. [http://dx.doi.org/10.1016/S2214-109X\(20\)30484-8](http://dx.doi.org/10.1016/S2214-109X(20)30484-8).

Supplemental Methods/Results 1:

Assessment of entry of clinical trials of COVID-19 treatment into more than one clinical trial registry

In order to assess the possible entry of clinical trials of treatment for COVID-19 in more than one clinical trial registry, we reviewed 100 clinical trial entries in the clinical trial registry with the largest number of registered clinical trials, www.clinicaltrials.gov.

We conducted a review of 108 of the eligible non-US-based clinical trials of COVID-19 treatment registered in www.clinicaltrials.gov. We assumed that duplicate entries of COVID-19 treatment clinical trials could have occurred in www.clinicaltrials.gov for two reasons: (1) this clinical trial registry contained hundreds more registered COVID-19 clinical trials than the next closest trial registry by frequency (Supplemental Table 1); (2) Non-US-based clinical trials are frequently registered in www.clinicaltrials.gov from countries from all regions, many of these regions also have nationally-based clinical trial registries.

Using the Excel spreadsheets created for the 10 focused registry search, we performed a trial-by-trial title review of 108 clinical trials of COVID-19 treatment by selecting key treatment terms in the title or using title phrases from www.clinicaltrials.gov. We then searched for these key terms in the country-based trial registries for China, UK, Brazil, India, and European countries. These trials were eligible and included in this study and were non-randomly selected from the spreadsheet containing all trials reviewed in www.clinicaltrials.gov. The frequencies of this review from www.clinicaltrials.gov to the country-based registry are noted below. Among these 108 clinical trials we found partial matches of title and content in another registry for 3 trials from France and 2 trials from Iran. We note that the trial registrations of these 5 trials were not exact duplicates within the two registries thus we cannot be certain of duplicate registration. From subsample cross registry search, we estimate that there is less than 5% duplicate registration of trials and that possible duplicate registration is not different by exclusion of pregnant women.

Table: Frequency of partial title match within two trial registries (n = 108)

Country of registration in www.clinicaltrials.gov	Name of trial registry cross-searched	Number of trials cross searched in national registry	Number of partial matches indicating possible duplicate registration
Brazil	ReBec	11	0
China	ChiCTR	13	0
European Countries			
<i>Austria</i>	EU-CTR	2	0
<i>Belgium</i>	EU-CTR	4	0
<i>Denmark</i>	EU-CTR	3	0
<i>France</i>	EU-CTR	18	3
<i>Germany</i>	EU-CTR	1	0

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

<i>Greece</i>	EU-CTR	4	0
<i>Netherlands</i>	EU-CTR	1	0
<i>Italy</i>	EU-CTR	11	0
<i>Spain</i>	EU-CTR	11	0
<i>Sweden</i>	EU-CTR	2	0
<i>Switzerland</i>	EU-CTR	1	0
India	CTRI	3	0
Iran	IRCT	13	2
UK	ISRCTN	7	0
Totals		108	5 (4.6%)

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Supplemental Table 1: Registered trials with “COVID” in the title from 21 WHO and ICMJE-accepted clinical trials registries				
	Time 1 (April 2020)		Time 2 (July 2020)	
Clinical Trial Registry	Number of clinical trials with COVID in title	Number of registered clinical trials with COVID and pregnant or pregnancy in title	Number of clinical trials with COVID in title	Number of registered clinical trials with COVID and pregnant or pregnancy in title
Australia and New Zealand's (ANZCTR)	15	1	91	5
Brazilian Clinical Trials Registry (ReBec)	4	0	30	0
Chinese Clinical Trial Registry (ChiCTR)	575	0	711	0
Clinical Research Information Service (CRiS), Korea	0	0	4	0
Clinical Trials Registry - India (CTRI)	7	0	298	0
Cuban Public Registry of Clinical Trials (RPCEC)	0	0	36	0
EU Clinical Trials Register (EU-CTR)	53	0	273	1
German Clinical Trials Register (DRKS)	Not accessible	N/A	465	0
Iranian Registry of Clinical Trials (IRCT)	72	0	281	0

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Japan Primary Registries Network	0	0	0	0
The Netherlands Trial Register	15	1	432	2
Pan African Clinical Trial Registry (PACTR)	1	0	19	0
Peruvian Registry of Clinical Trials	0	0	0	0
Philippine Health Research Registry	0	0	6	1
Sri Lanka Clinical Trials Registry (SLCTR)	0	0	1	0
South African National Clinical Trials Register	0	0	0	0
Swiss FOPH Human Research Projects	4	0	23	0
Tanzania Clinical Trial Registry	0	0	0	0
Thai Clinical Trials Registry	0	0	20	0
The United Kingdoms' ISRCTN registry	9	1	86	3
The United States' ClinicalTrials.gov	366	3	2713	25
Total	1121	6	5,492	40

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Supplemental Table 2a: Registered trials evaluating coronavirus in pregnant women, April 7–10, 2020				
Trial Name	Country	Design	Trial registry	Trial registry link
Prospective registry of maternal, perinatal and neonatal outcomes from pregnancies infected with SARS-COV2 (COVID-19)	Australia	Prospective Observational	ANZCTR	http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379572&isReview=true
COVID-19 PRIORITY (Pregnancy CoRonavirus Outcomes RegIsTrY) (PRIORITY)	USA	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04323839?term=pregnancy&cond=covid&draw=2&rank=1
Clinical Characteristics of Coronavirus Disease 2019 (COVID-19) in Pregnancy	Italy	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04319016?term=pregnancy&cond=covid&draw=2&rank=3
Clinical Characteristics of Coronavirus Disease 2019 (COVID-19) in Pregnancy: The Italian Registry on Coronavirus in Pregnancy.	Italy	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04315870?term=pregnancy&cond=covid&draw=2&rank=4
UKOSS: Pandemic COVID-19 in pregnancy, COVID-19 (SARS-CoV-2 infection) in pregnant women Pregnancy and Childbirth	UK	Observational cohort study	ISRCTN40092247	http://www.isrctn.com/ISRCTN40092247
COVID-19 during pregnancy: a prospective observational cohort	Netherlands	Observational cohort study	Trial NL8485	https://www.trialregister.nl/trial/8485

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Supplementary Table 2b: Registered trials evaluating COVID-19 in pregnant women as of July 10–15, 2020				
Trial Name	Country	Design	Trial registry	Trial registry link
Prospective registry of maternal, perinatal and neonatal outcomes from pregnancies infected with SARS-COV2 (COVID-19)	Australia	Prospective Observational	ANZCTR	http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379572&isReview=true
Has the threat of SARS COVID-19 increased influenza vaccination rates in pregnant women?	Australia	Cross-sectional study	ANZCTR	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379826&isReview=true
Simulation time taken amongst consultant anesthetists to perform spinal anesthesia or general anesthesia for COVID-19 patients requiring an emergency category 1 caesarean delivery	Australia	Randomized Controlled trial	ANZCTR	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379818&isReview=true
Neonatal CoVID-19 Study to evaluate the population health impacts of COVID-19 in mothers and their newborn infants cared for in tertiary and non-tertiary hospitals in Australia.	Australia	Prospective Observational study	ANZCTR	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379709&isReview=true
Risk Factors for Anxiety and Depression Among Pregnant Women During the COVID-19 Pandemic	Australia	Prospective Observational study	ANZCTR	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=18862&isClinicalTrial=True

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Hydroxychloroquine efficacy in preventing SARS-CoV-2 infection and CoVid-19 disease severity during pregnancy	EU	Randomized Controlled trial	2020-001587-29/SPAIN	https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001587-29/ES
COVID-19 PRIORITY (Pregnancy CoRonavIrus Outcomes RegIsTrY) (PRIORITY)	USA	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04323839?term=pregnancy&cond=covid&draw=2&rank=1
International Registry of Coronavirus (COVID-19) Exposure in Pregnancy (IRCEP)	USA	Prospective Cohort	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04366986?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=2
COVID-19 and Obstetric Transmission (COVIDOB)	USA	Case-control Study (Prospective)	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04418557?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=3
Assessing the Safety of Pregnancy In the CoRonavirus (COVID-19) pandEmic (ASPIRE)	USA	Prospective Cohort	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04388605?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=4
Health and Wellbeing of Pregnant and Post-Partum Women During the COVID-19 Pandemic	USA	Cross-sectional study	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04385238?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=5
In-Utero Vascular Accidents in Neonates From COVID-19 Infected Mothers	USA	Prospective Cohort	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04431869?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=6

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Risks of COVID19 in the Pregnant Population	USA	Observational Prospective Study	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04379284?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=7
Risk Factors for Anxiety and Depression Among Pregnant Women During the COVID-19 Pandemic (MindCOVID)	USA	Observational Prospective Study	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04377412?cond=COVID+19+and+pregnancy&cntry=US&draw=2&rank=8
Descriptive and Evaluation Study of the Use of Pulmonary Ultrasound in the Initial Management of Pregnant Women in the Context of COVID-19	USA (Marseille, France)	Cohort prospective study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04432805?cond=COVID-19+and+pregnant+women&draw=2&rank=1
Effect of Hydroxychloroquine in COVID	USA	Randomized Controlled Trial	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04354441?cond=COVID-19+and+pregnant+women&draw=2&rank=2
Postpartum Sexual Function in Pregnant Women With COVID-19	USA (Istanbul, Turkey)	Observational Prospective Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04389489?cond=COVID-19+and+pregnant+women&draw=2&rank=3
Obstetric and Perinatal Outcomes of Women With COVID-19	USA (Marseille, Paca, France)	Prospective Observational Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04369859?cond=COVID-19+and+pregnant+women&draw=2&rank=4
Investigation of the Relationship Between New Coronary Virus Disease (COVID-19) and Anxiety and Depressive Symptoms in Pregnant Women"	USA (Istanbul, Turkey)	Case- Control Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04384887?cond=COVID-19+and+pregnant+women&draw=2&rank=5

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Physical Activity Level, Stress Level, Sleep Quality in Pregnant Women During Covid-19 Quarantine	USA (Istanbul, Turkey)	Prospective Observational Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04336787?cond=COVID-19+and+pregnant+women&drow=2&rank=6
Characteristics of COVID-19 Infection Among PREGnant Women	USA	Prospective Cohort Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04398264?cond=COVID-19+and+pregnant+women&drow=2&rank=7
Evaluation of the Relationship Between Zinc Vitamin D and b12 Levels in the Covid-19 Positive Pregnant Women	USA (Istanbul, Turkey)	Case-Control Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04407572?cond=COVID-19+and+pregnant+women&drow=2&rank=8
Prevalence and Impact of COVID-19 Infection in Pregnant Women, Foetuses and New-borns	USA	Prospective Cohort Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04355234?cond=COVID-19+and+pregnant+women&drow=2&rank=9
Knowledge About Covid-19 Infection in Pregnant Women	USA (Giza, Egypt)	Cross-sectional study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04423692?cond=COVID-19+and+pregnant+women&drow=3&rank=11
D-dimer Levels in Pregnant With COVID-19	USA (Istanbul, Turkey)	Case-Control Study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04389554?cond=COVID-19+and+pregnant+women&drow=3&rank=12
Hydroxychloroquine Azithromycin COVID-19 Pregnancy Trial (HASCOPT)	USA (Marseille, France)	Randomized Controlled Trial	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04365231?cond=COVID-19+and+pregnant+women&drow=3&rank=13

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Prognosis in Pregnant With COVID-19	USA (Istanbul, Turkey)	Observational Study (Retrospective)	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04409249?cond=COVID-19+and+pregnant+women&draw=2&rank=14
Postoperative Recovery Index, Patient Expectations and Satisfaction With Prenatal Care Instrument in Pregnant Patients With COVID-19	USA (Istanbul, Turkey)	Prospective Study Observational	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04389515?cond=COVID-19+and+pregnant+women&draw=2&rank=15
Clinical and Immunologic Impact of Perinatal SARS-CoV-2 (COVID-19) Infection	USA	Case-control study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04362956?cond=COVID-19+and+pregnant+women&draw=2&rank=16
Assessment of Obstetric, Fetal and Neonatal Risks and Vertical SARS-CoV-2 Transmission During COVID-19 Pandemic (COroFet)	USA (Toulouse, France)	Clinical Trial (Non randomized)	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04360811?cond=COVID-19+and+pregnant+women&draw=2&rank=17
Northeast COVID-19 and Pregnancy Study Group (NCOVIP)	USA (Recife, Brazil)	Prospective Cohort study	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04462367?cond=Corona+virus+2+and+pregnant+women&draw=2&rank=2
Clinical Characteristics of Coronavirus Disease 2019 (COVID-19) in Pregnancy	Italy	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04319016?term=pregnancy&cond=covid&draw=2&rank=3

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Clinical Characteristics of Coronavirus Disease 2019 (COVID-19) in Pregnancy: The Italian Registry on Coronavirus in Pregnancy.	Italy	Observational Registry	clinicaltrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT04315870?term=pregnancy&cond=covid&draw=2&rank=4
Risk Factors for Anxiety and Depression Among Pregnant Women During the COVID-19 Pandemic	Italy	Prospective Cross-sectional study	clinicaltrials.gov	https://clinicaltrials.gov/ct2/show/NCT04377412?cond=COVID+19+and+pregnancy&cntry=IT&draw=2&rank=3
A Prospective International Lung UltraSound Analysis (ILUSA) Study in Tertiary Maternity Wards During the SARS-CoV-2 Pandemic	Italy	Prospective Cohort Study	clinicaltrials.gov	https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=18598&isClinicalTrial=True
UKOSS: Pandemic COVID-19 in pregnancy, COVID-19 (SARS-CoV-2 infection) in pregnant women Pregnancy and Childbirth	UK	Observational cohort study	ISRCTN40092247	http://www.isrctn.com/ISRCTN40092247

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

ISRCTN93266696 : Studying the immune response and long-term morbidity of COVID-19 infection in pregnancy	UK	Prospective Study	ISRCTN93266696	https://doi.org/10.1186/ISRCTN93266696
ISRCTN68026880 : A global registry of women affected by COVID-19 in pregnancy and their babies, to guide treatment and prevention	UK	Retrospective Study	ISRCTN68026880	http://www.isrctn.com/ISRCTN68026880?q=COVID-19%20and%20pregnant%20women&filters=&sort=&offset=7&totalResults=10&page=1&pageSize=10&searchType=basic-search
COVID-19 during pregnancy: a prospective observational cohort	Netherlands	Observational cohort study	Trial NL8485	https://www.trialregister.nl/trial/8485
Lifestyle of pregnant women during COVID-19 pandemic	Netherlands	Observational Study	Trial NL8668	https://www.trialregister.nl/trial/8668
Knowledge, practices, and risk and susceptibility perceptions on exposure to COVID-19: A qualitative triangulation study on pregnant women, their spouses, and non-pregnant reproductive-aged women with healthcare workers in Metro Manila	Philippines	Mixed-methods descriptive study	PHRR200604-002695	http://www.registry.healthresearch.ph/index.php/registry?view=research&layout=details&cid=2695

Appendix: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action (Taylor M, Kobeissi L, et al)

Supplemental Table 3: Exclusion of pregnant women from clinical trials of COVID-19 treatment using vitamins A, B-complex, C, D, and E.		
Trial Registry	Vitamin Trials Total	Vitamin Trials Excluding Pregnant women
The United Kingdoms' ISRCTN registry	0	0
Brazilian Clinical Trials Registry (ReBec)	0	0
The United States' ClinicalTrials.gov	15	12
Clinical Trials Registry - India (CTRI)	0	0
Australia and New Zealand's (ANZCTR)	1	0
Chinese Clinical Trial Registry (ChiCTR)	3	3
EU Clinical Trials Register (EU-CTR)	0	0
Iranian Registry of Clinical Trials (IRCT)	16	12
The Netherlands Trial Register	0	0
Swiss FOPH Human Research Projects	0	0
Totals	35	27