Hydroxychloroquine Efficacy and Safety in Preventing SARS-CoV-2 Infection and COVID-19 Disease Severity During Pregnancy and Postpartum (COVID-Preg)

ClinicalTrials.gov Identifier: NCT04410562

Recruitment Status : Recruiting
First Posted : June 1, 2020
Last Update Posted : January 22, 2021

See **Contacts and Locations**

Sponsor:
Barcelona Institute for Global Health

Collaborators:
Hospital Clinic of Barcelona
Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau
University Hospital of Torrejon

Fundación de investigación HM
Hospital Sant Joan de Deu
Hospital del Mar
Hospital Universitario Infanta Leonor
Hospital Universitario Fundación Alcorcón
Hospital General de Segovia
Institut Català de la Salut

Information provided by (Responsible Party):
Barcelona Institute for Global Health

Study Description

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Brief Summary:
It still unclear how SARS-CoV-2 affects pregnant women and their offspring, as well as which factors may influence obstetrical disease and outcomes, including the timing of maternal viral exposure by gestational age, the effects of parity, age, host immune responses, coexisting medical and obstetrical conditions and the effects of treatment regimens. While further information is gathered, based on the existing evidence from other infections causing pneumonia, pregnant women should be considered to be at high risk for developing severe infection during the current COVID-19 epidemic. Results from clinical trials with HCQ in nonpregnant adults may not be directly extrapolated to pregnant women given the special features of the pregnancy status. Thus, clinical research is urgently needed to improve the care and reduce the risk of poor pregnancy outcomes of women in this and in future epidemics.

Condition or disease	Intervention/treatment	Phase
Pregnancy Related COVID Covid-19	Drug: Hydroxychloroquine Drug: Placebo	Phase 3

Detailed Description:
This is a randomized, double blinded, placebo-controlled multicenter clinical trial including 714 pregnant women (200 SARS-CoV-2 infected -100 symptomatic with mild disease and 100 asymptomatic- pregnant women and 514 SARS-CoV-2 uninfected pregnant women who are contacts with a SARS-CoV-2 case) with the main objectives of assessing the safety and efficacy of oral hydroxychloroquine (HCQ) in reducing maternal viral shedding by PCR, and preventing incident SARS-CoV-2 infection and disease severity. Pregnant women undergoing antenatal follow up at five maternity hospitals, presenting at least one sign and/or one mild suggestive symptoms and a positive SARS-CoV-2 PCR test, or who are contacts of a suspected or confirmed case, will be recruited and randomized 1:1 to receive HCQ orally (400 mg/day for 3 days, followed by 200 mg/day for 11 days) or placebo. Women will be followed up for the duration of the intervention. One week after intervention completion, a SARS-CoV-2 PCR test will be repeated. At delivery, the

pregnancy outcome will be registered, and a cord blood sample will be collected to measure for IgG and IgM of SARS-CoV-2. A neonatal nasopharyngeal aspirate will be collected to perform PCR SARS-CoV-2 testing.

Study Design

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Study Type :

Interventional (Clinical Trial)

Estimated Enrollment :

714 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Intervention Model Description:

Randomized, double-blinded, placebo-controlled multicentre clinical trial.

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:

Treatment

Official Title:

Hydroxychloroquine Efficacy and Safety in Preventing SARS-CoV-2 Infection and COVID-19 Disease Severity During Pregnancy and Postpartum

Actual Study Start Date :

May 13, 2020

Estimated Primary Completion Date :

May 13, 2021

Estimated Study Completion Date :

August 1, 2021

Resource links provided by the National Library of Medicine

Drug Information available for: Hydroxychloroquine Hydroxychloroquine sulfate

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Hydroxychloroquine Participants will be then randomized in a 1:1 ratio to HCQ (400 mg/day for three days, followed by 200 mg/day for 11 days)	Drug: Hydroxychloroquine Participants will receive a bottle containing 19 tablets of study medication. They will be instructed to take two tablets for the first three days and one tablet for the following 11 days. (400 mg/day for three days, followed by 200 mg/day for 11 days). Other Name: Dolquine
Placebo Comparator: Placebo Participants will be then randomized in a 1:1 ratio to placebo (2 tablets for three days, followed by one tablet for 11 days).	Drug: Placebo Participants will receive a bottle containing 19 tablets of placebo. They will be instructed to take two tablets for the first three days and one tablet for the following 11 days.

Outcome Measures

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Primary Outcome Measures :

1. Number of PCR confirmed cases among pregnant women [Time Frame: 21 days after intervention]

   Number of PCR-confirmed infected pregnant women assessed from collected nasopharyngeal and oropharyngeal swabs at day 21 after treatment start

Secondary Outcome Measures :

1. Incidence of COVID-19 disease during pregnancy [Time Frame: through study completion, an average of 1 year]
2. Incidence of COVID-19-related admissions [Time Frame: through study completion, an average of 1 year]
3. Incidence of all-cause admissions [Time Frame: through study completion, an average of 1 year]
4. Incidence of all-cause outpatient attendances [Time Frame: through study completion, an average of 1 year]
5. Mean duration of symptoms-signs of COVID-19 [Time Frame: through study completion, an average of 1 year]

6. Frequency and severity of adverse events [Time Frame: through study completion, an average of 1 year]
7. Incidence of preeclampsia [Time Frame: through study completion, an average of 1 year]
8. Incidence of gestational diabetes [Time Frame: through study completion, an average of 1 year]
9. Incidence of SARS-CoV-2 infections during pregnancy [Time Frame: through study completion, an average of 1 year]
10. Prevalence of intrauterine growth restriction [Time Frame: through study completion, an average of 1 year]
11. Maternal mortality rate [Time Frame: through study completion, an average of 1 year]
12. Proportion of neonates with SARS-CoV-2- intrauterine infection by PCR-confirmed SARS-CoV-2-infection in nasopharyngeal aspirate. [Time Frame: through study completion, an average of 1 year]
13. Proportion of neonates with clinical signs/symptoms of COVID-19 [Time Frame: through study completion, an average of 1 year]
14. Prevalence of low birth weight (<10th centile according to local standards) [Time Frame: through study completion, an average of 1 year]
15. Prevalence of preterm birth (<37 weeks of gestational age) [Time Frame: through study completion, an average of 1 year]
16. Prevalence of embryo and foetal losses (miscarriages and stillbirths) [Time Frame: through study completion, an average of 1 year]
17. Frequency of congenital malformations [Time Frame: through study completion, an average of 1 year]
18. Proportion of adverse perinatal outcome [Time Frame: through study completion, an average of 1 year]
19. Neonatal morbidity [Time Frame: through study completion, an average of 1 year]
20. Neonatal mortality rate [Time Frame: through study completion, an average of 1 year]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

Child, Adult, Older Adult

Sexes Eligible for Study:

Female

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Presenting with fever (≥37.5ºC) and/or one mild symptom suggestive of COVID-19 disease (cough, dyspnoea, chills, odynophagia, diarrhoea, muscle pain, anosmia, taste disorder, headache) OR contact of a SARS-CoV-2 confirmed or suspected case in the past 14 days
- More than 12 weeks of gestation (dated by ultrasonography)
- Agreement to deliver in the study hospitals

Exclusion Criteria:

- Known hypersensitivity to HCQ or other 4-aminoquinoline compounds
- History of retinopathy of any aetiology
- Concomitant use of digoxin, cyclosporine, cimetidine
- Known liver disease
- Clinical history of cardiac pathology including known long QT syndrome
- Unable to cooperate with the requirements of the study
- Participating in other intervention studies
- Delivery onset (characterized by painful uterine contractions and variable changes of the cervix, including some degree of effacement and slower progression of dilatation up to 5 cm for first and subsequent labours)

Contacts and Locations

Go to

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04410562***

Contacts

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Locations

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Hospital del Mar — **Recruiting**
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Sponsors and Collaborators

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More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

González R, García-Otero L, Pons-Duran C, Marbán-Castro E, Goncé A, Llurba E, Gil MDM, Rodríguez-Zambrano MÁ, Chen H, Ramírez M, Bardají A, Menendez C. Hydroxychloroquine efficacy and safety in preventing SARS-CoV-2 infection and COVID-19 disease severity during pregnancy (COVID-Preg): a structured summary of a study protocol for a randomised placebo controlled trial. Trials. 2020 Jul 2;21(1):607. doi: 10.1186/s13063-020-04557-y.

Responsible Party:
Barcelona Institute for Global Health

ClinicalTrials.gov Identifier:
NCT04410562 History of Changes

Other Study ID Numbers:
2020-001587-29

First Posted:
June 1, 2020 Key Record Dates

Last Update Posted:
January 22, 2021

Last Verified:
April 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Yes

Plan Description:

It would be shared at time of publication.

Supporting Materials:

Study Protocol

Statistical Analysis Plan (SAP)

Informed Consent Form (ICF)

Clinical Study Report (CSR)

Time Frame:

By the end of study

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Barcelona Institute for Global Health:

pregnancy

covid-19

coronavirus

hydroxychloroquine

Additional relevant MeSH terms:

Infection

Hydroxychloroquine

Antimalarials

Antiprotozoal Agents

Antiparasitic Agents

Anti-Infective Agents

Enzyme Inhibitors

Molecular Mechanisms of Pharmacological Action

Antirheumatic Agents