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An international registry of coronavirus exposure in pregnancy

Submission date	Recruitment status	[_] Prospectively registered
26/10/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2023	Infections and Infestations	

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

There is insufficient information on the potential effects of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection on pregnant women and their developing offspring. However, these populations are classified as vulnerable.
The International Registry of Coronavirus Exposure in Pregnancy (IRCEP) aims to describe the natural history of Coronavirus Disease 2019 (COVID-19) in pregnant women and to estimate the risk of major pregnancy-related outcomes among women with varying degrees of severity and of timing of COVID-19 exposure.

Who can participate?
Adult pregnant women with clinical confirmation of COVID-19 or tested for SARS-CoV-2 at any time during their pregnancy.

What does the study involve?
Registration and participation will be via the website or mobile app specially developed for the IRCEP. The IRCEP will collect data on the mother's social background, behaviors, reproductive history, chronic conditions, use of medications, and of healthcare utilization, on COVID-19 infection (symptoms, test results, treatment, and resolution), and information related to pregnancy, childbirth, and the health of the child. Follow-up will include questions at various time points during the pregnancy and will continue through the infant's first 90 days of life.

What are the possible benefits and risks of participating?
Benefits: By joining the IRCEP and answering the questions, participants can help improve care for other pregnant women with COVID-19 in the future. Additionally, participants will be able to see how their pregnancy experiences compare to those of other women in the study, since aggregate results of the Registry will be reported to participants.
Risks: There are no known physical risks of taking part in the IRCEP. But, like any online activity, there is always a risk of loss of privacy.

Where is the study run from?
Pregistry LLC (USA)

When is the study starting and how long is it expected to run for?
March 2020 to June 2022

Who is funding the study?
Pregistry LLC (USA)

Who is the main contact?
Dr Diego Wyszynski, hello@pregistry.com

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Public

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ClinicalTrials.gov (NCT)
NCT04366986

Study information

Scientific Title
International Registry of Coronavirus Exposure in Pregnancy (IRCEP)

Acronym
IRCEP

Study objectives
COVID-19 during pregnancy increases the risk of obstetrical, neonatal, and infant abnormal outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2020, Institutional Review Board (IRB) of the Harvard T.H. Chan School of Public Health (90 Smith Street, 3rd Floor Boston, MA 02120, USA; +1 (617) 432-5132; kninsala@hsph.harvard.edu), ref: # IRB20-0622

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) during pregnancy

Interventions
The IRCEP will be an observational cohort study with prospective and retrospective components. Registration and participation via website or mobile app specially developed for the IRCEP will be voluntary. Women 18 years of age and older will be encouraged to enrol if at any time during pregnancy, they had a test performed for the coronavirus (regardless of the result) or if they had clinical confirmation of COVID-19 in the absence of a SARS-CoV-2 test. Women with confirmed COVID-19 via clinical or test methods will be included in the exposed group and women with a negative test will be included in the control group. Eligible women will be able to enrol at any time during gestation. Given the public health emergency due to the COVID-19 pandemic and the urgent need for data, the IRCEP will also enrol eligible women retrospectively during the first 180 days after delivery (if they delivered after December 2019).

As numbers accumulate, the natural history of COVID-19 during pregnancy will be reported stratified by days since COVID-19 confirmation at enrollment (i.e., from prospective if immediate to retrospective if enrolled after resolution) and the risk of pregnancy outcomes by COVID-19 exposure group will be reported stratified by trimester at enrollment. For the assessment of miscarriages, only participants enrolled during the first trimester will be included and the analyses will be stratified by gestational week at enrollment. For other outcomes, the primary analysis will include all enrollees. However, sensitivity analyses of 1) teratogenicity will be restricted to participants enrolled before an informative prenatal screening was done; 2) late-pregnancy outcomes (e.g. preeclampsia) will be restricted to participants enrolled before the third trimester; and 3) delivery or neonatal outcomes will be restricted to participants enrolled before delivery.

Information will be obtained directly from the participating women. Given the international nature of the IRCEP, the questionnaires will be available in 7 languages (English, Spanish, French, German, Italian, Mandarin, and Farsi). Participant confidentiality and anonymity will be strictly upheld. The IRCEP will collect data on potential confounding factors (such as maternal sociodemographic characteristics, behaviors, reproductive history, chronic conditions, use of medications, and measures of healthcare utilization), on COVID-19 infection (symptoms, test results, treatment, and resolution), and information related to obstetric and neonatal outcomes. Follow-up will include questions at various time points during the pregnancy and will continue through the infant's first 90 days of life.

There are two main data analyses: 1) a real-time descriptive surveillance that will report the COVID-19 characteristics and the frequency of outcomes in the exposed and control groups, and 2) hypothesis-based causal inference analyses that will investigate the potential effects of specific COVID-19 characteristics or treatments and will adjust through multivariate regression models or using propensity score (PS) matching to account for potential confounders, as appropriate.

Intervention Type
Other

Primary outcome(s)
Measured by maternal self-report using online questionnaire at baseline:
1. Pregnancy outcomes:
1.1. Miscarriage (or spontaneous abortion)
1.2. Elective termination
1.3. Stillbirth

1.4. Preterm delivery
2. Birth outcomes (measured at additional time points up to 90 days):
2.1. Major structural defects
2.2. Neonatal death
2.3. Admission into the Neonatal Intensive Care Unit
2.4. Maternal obstetric complications
2.5. Post-partum health

Key secondary outcome(s))
Measured by maternal self-report using online questionnaire:
1. Head circumference (cm) at each time point from baseline to 90 days.
2. Length at birth (cm)

Completion date
30/06/2022

Eligibility

Key inclusion criteria
Adult pregnant women with clinical confirmation of COVID-19 or tested for SARS-CoV-2 at any time during their pregnancy

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
18000

Key exclusion criteria
Subjects who do not meet the inclusion criteria

Date of first enrolment
08/06/2020

Date of final enrolment

30/06/2022

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Scotland

Wales

Afghanistan

Åland Islands

Albania

Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Australia

Austria

Azerbaijan

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

Benin

Bermuda

Bhutan

Bolivia

Bonaire Saint Eustatius and Saba

Bosnia and Herzegovina

Botswana

Bouvet Island

Brazil

British Indian Ocean Territory

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Cayman Islands

Central African Republic

Chad

Chile

China

Christmas Island

Cocos (Keeling) Islands

Colombia

Comoros

Congo

Congo, Democratic Republic

Cook Islands

Costa Rica

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Côte d'Ivoire

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

Equatorial Guinea

Eritrea

Estonia

Eswatini

Ethiopia

Falkland Islands

Faroe Islands

Fiji

Finland

France

French Guiana

French Polynesia

French Southern Territories

Gabon

Gambia

Georgia

Germany

Ghana

Gibraltar

Greece

Greenland

Grenada

Guadeloupe

Guam

Guatemala

Guernsey

Guinea

Guinea-Bissau

Guyana

Haiti

Heard Island and McDonald Islands

Holy See (Vatican City State)

Honduras

Hong Kong

Hungary

Iceland

India

Indonesia

Iran

Iraq

Ireland

Isle of Man

Israel

Italy

Jamaica

Japan

Jersey

Jordan

Kazakhstan

Kenya

Kiribati

Korea, North

Korea, South

Kosovo

Kuwait

Kyrgyzstan

Lao People's Democratic Republic

Latvia

Lebanon

Lesotho

Liberia

Libya

Liechtenstein

Lithuania

Luxembourg

Macao

Madagascar

Malawi

Malaysia

Maldives

Mali

Malta

Marshall Islands

Martinique

Mauritania

Mauritius

Mayotte

Mexico

Micronesia, Federated States of

Moldova

Monaco

Mongolia

Montenegro

Montserrat

Morocco

Mozambique

Myanmar

Namibia

Nauru

Nepal

Netherlands

New Caledonia

New Zealand

Nicaragua

Niger

Nigeria

Niue

Norfolk Island

North Macedonia

Northern Mariana Islands

Norway

Oman

Pakistan

Palau

Palestine, State of

Panama

Papua New Guinea

Paraguay

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Romania

Russian Federation

Rwanda

Réunion

Saint Barthélemy

Saint Helena, Ascension and Tristan da Cunha

Saint Kitts and Nevis

Saint Lucia

Saint Martin (French part)

Saint Pierre and Miquelon

Saint Vincent and the Grenadines

Samoa

San Marino

Sao Tome and Principe

Saudi Arabia

Senegal

Serbia

Seychelles

Sierra Leone

Singapore

Sint Maarten (Dutch part)

Slovakia

Slovenia

Solomon Islands

Somalia

South Africa

South Georgia and the South Sandwich Islands

South Sudan

Spain

Sri Lanka

Sudan

Suriname

Svalbard and Jan Mayen

Sweden

Switzerland

Syria

Taiwan

Tajikistan

Tanzania

Thailand

Timor-Leste

Togo

Tokelau

Tonga

Trinidad and Tobago

Tunisia

Turkmenistan

Turks and Caicos Islands

Tuvalu

Türkiye

Uganda

Ukraine

United Arab Emirates

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Study participating centre

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Sponsor information

Organisation
Pregistry LLC

Funder(s)

Funder type
Industry

Funder Name
Pregistry LLC

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the International Registry of Coronavirus Exposure in Pregnancy (ircep@pregistry.com). De-identified data will be provided to applicants who submit a research study protocol approved by the Registry's Leadership Team and the Scientific Advisory Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/10/2022	17/07/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes