ISRCTN11700499 https://doi.org/10.1186/ISRCTN11700499

A UK-wide, direct-to-patient platform for studying cardiovascular disease in pregnancy

Submission date
24/11/2025

Recruitment status
Recruiting

Registration date
26/11/2025

Overall study status
Ongoing

Last Edited
26/11/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to improve our understanding of the impact of cardiovascular (heart) disease on pregnancy, on the long-term effects of pregnancy on women with cardiovascular disease, and on how best to treat and manage cardiovascular disease during pregnancy and the postnatal period. Up to 4% of pregnant women have cardiovascular disease, and cardiovascular disease in pregnancy is a leading cause of harm for mothers and babies. However, because there are many different types of cardiovascular disease which can affect pregnant women, and these women live in different parts of the country and receive care in different hospitals, it is difficult for studies to recruit enough women with specific cardiovascular conditions for research. This makes it hard for researchers to build an understanding of how these diseases behave in pregnancy and to develop better treatments.
The purpose of this study is therefore to create an online research platform where women with cardiovascular disease in pregnancy, alongside women without cardiovascular disease (to act as a healthy control group), can self-identify, provide consent to share information about their health and pregnancies, and agree to participate in research. This will help to remove some of the barriers to participation in research for this patient group (for example, barriers associated with living in particular parts of the country, receiving care in certain hospitals, or not having the means to travel to participate in research visits).

Who can participate?
Women aged 16 years or older are eligible to take part in the study if:
1. They are currently or have previously been pregnant, and have cardiovascular disease which was diagnosed prior to, during, or in the 6 months after pregnancy (cases); OR
2. They are currently pregnant, with no diagnosis of cardiovascular disease (healthy controls)

What does the study involve?
Participants will be invited to register on an online platform (PREG-HEART), provide consent electronically, and enter information about themselves, their health, and their current and/or previous pregnancies.
Information about the health of participants, and the outcome of their pregnancies, will be collected using questionnaires which they will be invited to complete when they register on the platform, after the end of their pregnancy, and up to once a year following this.

Participants will also be able to give their consent to provide samples (for example of blood, urine, or saliva) for future research use. They may also give consent to be contacted in order to be invited to participate in additional studies about cardiovascular health in pregnancy.

What are the possible benefits and risks of participating?
There will be no direct benefits from taking part in this study, but the results may help to improve the healthcare of pregnant women in the future. As this is an observational study, the risk of adverse effects due to participation are unlikely to occur.

Where is the study run from?
The National Heart and Lung Institute, Imperial College London (UK)

When is the study starting and how long is it expected to run for?
The study is starting in November 2025 and aims to create a research platform which will run indefinitely

Who is funding the study?
British Heart Foundation and National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Upasana (Paz) Tayal, preg-heart@imperial.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Upasana Tayal

ORCID ID
https://orcid.org/0000-0003-2262-4626

Contact details
Imperial College London
Genetics and Genomics Office
Royal Brompton Campus
Sydney Street
London
United Kingdom
SW3 6NP
-
preg-heart@imperial.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
349694

Protocol serial number

176975

Study information

Scientific Title
PREG-HEART: PREGnancy, HEART health and cardiovascular disease longitudinal study

Acronym
PREG-HEART

Study objectives
The objectives of this study are:
1. To evaluate the feasibility of recruiting, engaging, and retaining a geographically diverse, heterogenous cohort of pregnant or recently pregnant women with and without cardiovascular disease using a direct-to-patient online platform
2. To begin to characterise the natural history of different forms of cardiovascular disease in pregnancy across the UK, and to assess regional and institutional variation in management and outcomes
3. To provide a national capacity to recontact participants for later studies and biosample collection, to allow multiomic approaches with the goal of identifying new molecular mechanisms of disease and improving approaches to disease stratification

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/10/2025, West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8191; solihull.rec@hra.nhs.uk), ref: 25/WM/0142

Study design
Direct-to-patient online research platform, through which eligible participants can be recruited to a longitudinal observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiovascular disease in pregnancy

Interventions
Participants will be invited to register on the online PREG-HEART platform, provide consent electronically, and enter self-reported demographics and health data relevant to their cardiovascular diagnosis and current/previous pregnancies.

Participant-reported baseline demographic and health data will be collected via online questionnaire at registration, following pregnancy completion, and up to annually thereafter.

Participants will also be given the option to consent to collection of biosamples (such as blood, saliva, and urine) for storage and analysis, and to collection of data through linkage to national registries and medical records.

Participants may also consent to be recontacted for the purpose of being invited to consider participation in further investigator-initiated studies for which they are likely to be eligible.

Intervention Type
Other

Primary outcome(s)
The primary outcome is to evaluate the feasibility of direct-to-patient recruitment to a longitudinal cohort study of cardiovascular disease in pregnancy. This will be measured by assessing the following after a 6-month pilot period, and annually thereafter:
1. Number of participants (cases and controls) successfully recruited, baseline questionnaire completion rate, and number of biosamples provided
2. The primary self-reported cardiovascular diagnoses of recruited participants, compared to estimated UK prevalences based on nationally reported data

Key secondary outcome(s))
Pregnancy outcome data for recruited participants (collected through participant-report and/or linkage to national registries and medical records), compared to nationally reported outcome data for women with cardiovascular disease. This will be assessed at the end of the initial 6-month pilot period, and annually thereafter.

Completion date
30/11/2028

Eligibility

Key inclusion criteria
1. Adult (age 16 years and over)
2. Registered with a GP in the UK
3. Capacity to provide informed consent

For those enrolling as participants with cardiovascular disease (cases):
1. Any history of pregnancy, either current or previous (with pregnancy defined as a positive pregnancy test and/or ultrasound confirmed pregnancy)
2. Self-reported confirmed diagnosis of cardiac disease which predates pregnancy, or was newly diagnosed during pregnancy or within 6 months postpartum, including:
2.1. Ventricular dysfunction (cardiomyopathies, heart failure of any aetiology)
2.2. Valvular heart disease (including previous valve replacement)
2.3. Congenital cardiac lesions (including following surgical correction of congenital lesion)
2.4. Arrhythmia (cardiac conduction defects and arrhythmias history of previous cardiac ablation, inherited arrhythmia syndromes)
2.5. Coronary artery disease
2.6. Systemic hypertension
2.7. Pulmonary hypertension
2.8. Aortic disease
2.9. Connective tissue disease (heritable collagen, elastin, or glycosaminoglycan disorders, autoimmune connective tissue diseases and vasculitides)

2.10. Thromboembolic disease
2.11. Other relevant long-term cardiac diagnoses as determined by the study investigators
2.12. Carriers of (pathogenic) genetic variants associated with cardiovascular conditions

For those enrolling as participants without cardiac disease (controls):
1. Currently pregnant (with pregnancy defined as a positive pregnancy test and/or ultrasound confirmed pregnancy)
2. No diagnosed cardiac disease, as defined by the conditions listed above

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Patients who lack capacity to consent for themselves
2. People who do not have access to the Internet and/or who are unable to provide an email address for study correspondence

Date of first enrolment
25/11/2025

Date of final enrolment
31/01/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
N/A - this is an online platform study therefore there are no research sites
-

-
England
-

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (the Heart Hive).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			26/11/2025	No	No