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Study to establish reference ranges for pregnancy for blood tests

Submission date
10/02/2022

Recruitment status
No longer recruiting

Registration date
07/03/2022

Overall study status
Completed

Last Edited
03/04/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A woman's body changes through pregnancy. This means the levels of many different hormones and other substances in the blood vary in pregnancy. Doctors, midwives, and other people who look after pregnant women should use reference ranges for these blood markers that are specific to each trimester of pregnancy, and not just use the ranges used for the non-pregnant population. This is in line with international guidance. We are therefore asking healthy pregnant women to given a sample of blood or urine so that we can provide up-to-date reference ranges for blood tests in pregnancy.

In particular we plan to make reference ranges for levels of different thyroid hormones. Thyroid hormone is vital for the neurological development of the baby, so ensuring that a mother's thyroid hormone levels are normal is essential. We will also measure urine iodine levels as these affect how the body makes thyroid hormones. We also plan to measure some blood pressure hormones (renin and aldosterone) and a heart marker (troponin). We know that more women are suffering from blood pressure problems and heart disease in pregnancy, so being able to diagnoses these accurately is really important for good care of the mother.

Who can participate?
Women over 18 years of age with singleton pregnancies who are receiving antenatal care at Imperial College London NHS Trust.

What does the study involve?
Participants are asked to give an extra sample of blood during their routine blood tests in pregnancy. These samples are stored and then routine biochemical analytes (such as thyroid hormone levels) will be ascertained by running through a laboratory analyser.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
February 2021 to February 2023

Who is funding the study?
Abbott Laboratories (USA)

Who is the main contact?
Prof. Tricia Tan, rebecca.scott22@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Prof Tricia Tan

Contact details
Department of Digestion, Metabolism and Reproduction
6th Floor Commonwealth Building,
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0NN
+44 7970742784
rebecca.scott22@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287069

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 287069, CPMS 47473

Study information

Scientific Title
Pregnancy Reference Ranges Study

Acronym
PREGRRS

Study objectives
The aim of this study is to establish accurate, trimester specific reference ranges for biochemical analytes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2021, East of England Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048227; essex.rec@hra.nhs.uk), ref: 20/EE/0260

Study design
Cross sectional laboratory study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Looking at normal ranges in healthy pregnancy

Interventions
Women who are pregnant will be asked, as a one off, to given an extra sample of blood at the time that they have routine blood tests in pregnancy, plus in some instances a urine sample at the same time. They will also be asked to complete a brief, online questionnaire about their pregnancy and underlying health. The blood and urine samples will be stored, before being processed to establish levels of certain routine biochemical markers at each stage in pregnancy. Once the women have given their sample and completed the questionnaire, their participation in the study is complete.

Intervention Type
Other

Primary outcome measure
Levels of biochemical analytes in sampled blood will be analysed in accordance with national/international guidance:
1. Thyroid function - TSH, free T3, free T4
2. Thyroid peroxidase antibodies

3. Renin
4. Aldosterone
5. Folate
6. Iron
7. Troponin
8. Iodine

Secondary outcome measures
Gestation of the pregnancy, the mother’s underlying health, and some demographic data measured at a single time point using a questionnaire

Overall study start date
01/02/2021

Completion date
01/02/2023

Eligibility

Key inclusion criteria
1. Women over 18 years of age who are receiving antenatal care at Imperial College London NHS Trust
2. Singleton pregnancies

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1200

Total final enrolment
725

Key exclusion criteria
1. Multiple pregnancies
2. Current or previous history of thyroid disease
3. Current or previous use of thyroid medications
4. Inability to understand and write in the English Language
5. Unable to participate for other factors as assessed by the Chief Investigators

Date of first enrolment

07/04/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Sponsor information

Organisation
Imperial College London

Sponsor details
Room 215, Level 2
Medical School Building
Norfolk Place
London
England
United Kingdom
W2 1PG
+44 2075949459
becky.ward@imperial.ac.uk

Sponsor type
University/education

Website
http://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal
Results will also be disseminated throughout the ICS

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
If requested from Chief Investigators (rebecca.scott22@nhs.net)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Participant questionnaire version 1.0	01/01/2021	11/02/2022	No	No
Participant information sheet	version 2.0	07/01/2021	11/02/2022	No	Yes
Protocol file	version 2.0	01/01/2021	11/02/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		28/03/2025	01/04/2025	Yes	No