

# Study to establish reference ranges for pregnancy for blood tests

<b>Submission date</b> 10/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/04/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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 give 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 diagnose 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

287069

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Other

## **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 give 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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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**

United Kingdom

England

**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

**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

**Individual participant data (IPD) sharing plan**  
If requested from Chief Investigators ([rebecca.scott22@nhs.net](mailto:rebecca.scott22@nhs.net))

## IPD sharing plan summary

Available on request

### Study outputs

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