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# Investigating hormones triggering the onset of sustained lactation

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 28/06/2021 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 07/07/2021 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/10/2023 | Pregnancy and Childbirth | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Breastfeeding is controlled by hormones that trigger the start of milk secretion (known as secretory activation) within the first few days after giving birth. Delayed secretory activation is a major cause of breastfeeding failure. However, the hormone levels required for secretory activation and successful breastfeeding are unknown. The INSIGHT pilot study will assess the feasibility of collecting maternal blood samples for hormone measurements within the first days after giving birth and the main INSIGHT study will establish the reference intervals for hormone levels in the blood during the first 4 days after giving birth.

Who can participate?
Pregnant women aged 18 and over who are intending to breastfeed

What does the study involve?
The researchers will take a blood sample during the third trimester, and then collect blood samples before and after a breastfeed on each of the first 4 days after giving birth. They would also like to obtain a urine and breast milk sample on day 4 after giving birth. Each participant will be asked to keep a diary of when her milk comes in.

Where is the study run from?
The Women's Centre at the John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2020 to July 2024

Who is funding the study?
The Family Larsson-Rosenquist Foundation (Switzerland)

Who is the main contact?
Prof. Fadil Hannan
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## Study website

https://www.ocehl.ox.ac.uk/

# Contact information

### Type(s)
Scientific


### Contact name
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
278264

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRAS 278264, PID 14930

# Study information

### Scientific Title
Investigating hormones triggering the onset of sustained lactation

### Acronym
INSIGHT

### Study objectives

Current study hypothesis as of 11/08/2022:
Breastfeeding is a hormonally controlled process that is important for promoting infant growth and development and reducing the maternal risk of diseases such as diabetes and breast cancer. However, the hormone concentrations required to initiate lactation in the early postpartum period are unknown. The INSIGHT study involves an initial pilot phase to evaluate the feasibility of sample collection in the early postpartum period. The main study phase will characterise lactation hormone concentrations at the onset of copious milk secretion during the first 4 days post-partum. The INSIGHT study aims to establish reference intervals for hormones initiating lactation in the early postpartum period.

Previous study hypothesis:
Breastfeeding is a hormonally controlled process that is important for promoting infant growth and development and reducing the risk of diseases such as diabetes and breast cancer in the mother. This pilot observational study will evaluate the feasibility of sample collection in the early postpartum period for defining lactation hormone concentrations at the onset of copious milk secretion.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 11/09/2020, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8096, +44 (0)207 104 8106, +44 (0)207 104 8265; cambsandherts.rec@hra.nhs.uk), REC ref: 20/EE/0172

## Study design
Observational study with an internal pilot feasibility study

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
See study output table

## Health condition(s) or problem(s) studied
Breastfeeding

## Interventions
Current intervention as of 10/08/2022:
The INSIGHT study involves the following study procedures:

Baseline (pregnancy):
Blood sample collection on a single occasion during late pregnancy

Postpartum:
1. Self-recording of breast fullness during postpartum days 1-4
2. Blood sample collection before and after a breastfeed on postpartum days 1-4
3. Spot urine sample collection on postpartum day 4
4. Breast milk collection on postpartum day 4

Previous intervention:
The INSIGHT pilot study involves the following study procedures:

Baseline (pregnancy):
Blood sample collection on a single occasion during late pregnancy

Postpartum:
1. Self-recording of breast fullness during postpartum days 1-4
2. Blood sample collection before and after a breastfeed on postpartum day 4
3. Spot urine sample collection on postpartum day 4
4. Breast milk collection on postpartum day 4

## Intervention Type
Other

## Primary outcome measure
Current primary outcome measure as of 10/08/2022:
INSIGHT study:
Serum hormone reference intervals established by parametric or non-parametric analysis during the first 4 days post-partum

INSIGHT pilot study:
Feasibility of postpartum sample collection: assessed using the proportion of participants willing to be recruited and provide samples on the 4th day postpartum

Previous primary outcome measure:
Feasibility of postpartum sample collection: assessed using the proportion of participants willing to be recruited and provide samples on the 4th day postpartum

## Secondary outcome measures
Current secondary outcome measures as of 10/08/2022:
INSIGHT study:
The following outcomes will be measured using biochemical analysis during the first 4 days post-partum:
1. Longitudinal changes in serum lactation hormones
2. Associations between serum lactation hormones and maternal co-morbidities, medications, mode of delivery, or pregnancy complications
3. Serum lactation hormone concentrations correlated with timing of onset of milk production
4. Breast milk hormone composition
5. Serum lactation hormones correlated with breast milk volume.

INSIGHT pilot study:
1. Lactation hormones measured by immunoassay in blood and urine samples on the 4th day

postpartum
2. Breast milk hormones and bioactive molecules measured by immunoassay in breast milk samples on the 4th day postpartum

Previous secondary outcome measures:
1. Lactation hormones measured by immunoassay in blood and urine samples on the 4th day postpartum
2. Breast milk hormones and bioactive molecules measured by immunoassay in breast milk samples on the 4th day postpartum

### Overall study start date
01/03/2020

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
1. Pregnant women, aged ≥18 years
2. Term singleton pregnancy (≥37 weeks gestation)
3. Intention to fully or partially breastfeed
4. Willing and able to give informed consent for participation in the study

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
1068

### Key exclusion criteria
1. Severe maternal illness including diagnosis of postpartum depression or psychosis
2. Severe infant illness including major congenital abnormalities and infants who are only expected to live for a short period of time
3. Prolonged separation of infant from mother e.g. due to admission to the neonatal unit
4. Major COVID-19 symptoms e.g. pyrexia and continuous cough
5. Mother or infant infected with blood-borne viruses such as HIV
6. Resides outside of Oxfordshire
7. Safeguarding issues that may impede the safety of research staff carrying out home visits
8. Current participation in another research study that involves investigational medicinal products

### Date of first enrolment
01/09/2021

### Date of final enrolment
01/07/2024

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Oxford University Hospitals NHS Foundation Trust**
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

## Sponsor information

### Organisation
University of Oxford

### Sponsor details
Joint Research Office
Clinical Trials and Research Governance (CTRG)
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### Sponsor type
University/education

### Website
https://researchsupport.admin.ox.ac.uk/ctrg#/

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Charity

**Funder Name**
Family LarssonRosenquist Foundation

**Alternative Name(s)**
Familie Larsson-Rosenquist Stiftung, LarssonRosenquist Foundation, The Family Larsson-Rosenquist Foundation, Family Larsson Rosenquist Foundation, FLRF, FLRS

**Funding Body Type**
Private sector organisation

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

**Location**
Switzerland

# Results and Publications

**Publication and dissemination plan**
Planned publication at a high-impact peer-reviewed journal. The researchers are also planning to publish the study protocol.

**Intention to publish date**
01/09/2026

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available. The main aim of this pilot study is to assess the feasibility of participant recruitment and sample collection. Therefore, there may be little or no participant-level data. In addition, the consent form does not specify sharing of any participant-level data.

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V1.0 | 28/04/2021 | 08/07/2021 | No | Yes |

| | | | | |
|---|---|---|---|---|
| Protocol article | 30/08/2022 | 31/08/2022 | Yes | No |
| HRA research summary | | 28/06/2023 | No | No |