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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
fadil.hannan@wrh.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Fadil Hannan

ORCID ID
https://orcid.org/0000-0002-2975-5170

Contact details
Nuffield Department of Women's and Reproductive Health
University of Oxford
Level 4, Women's Centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 222937
fadil.hannan@wrh.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
278264

Protocol serial number
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

Primary study design
Observational

Study design
Observational study with an internal pilot feasibility study

Study type(s)
Other

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington

Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Family LarssonRosenquist Foundation

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

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

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?
Protocol article		30/08/2022	31/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.0	28/04/2021	08/07/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes