

# Evaluation of laboratory methods for measuring the composition of breastmilk

<b>Submission date</b> 27/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/03/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Human milk is a nutrient-rich fluid that also contains hormones, cells, antibodies, and metabolites that are transmitted to the breastfeeding infant. These milk components have the potential to influence development of the newborn. However, little is known about the overall composition of these factors within human milk. The aim of this study is the establishment of laboratory methods, which can be used in future clinical studies to investigate the biological mechanisms by which breastfeeding can influence the health and wellbeing of the infant.

### Who can participate?

Healthy volunteers, who are mothers in established lactation

### What does the study involve?

A breastfeeding mother will be asked to express 5-10 ml of milk. This sample will be used to evaluate a range of laboratory tests for measuring hormones, cells, antibodies, and metabolites in human milk. Normally the researchers would ask participants to provide a breast milk sample on a single occasion. However, if a mother is producing substantial amounts of breast milk, then they may ask if she is willing to provide additional samples.

### What are the possible benefits and risks of participating?

The main benefit of this study is to develop better methods for measuring hormones and other factors contained in breast milk. This study is not expected to cause any adverse effects.

### Where is the study run from?

The University of Oxford (UK)

### When is the study starting and how long is it expected to run for?

September 2019 to January 2024

### Who is funding the study?

The Family Larsson Rosenquist Foundation (Switzerland)

Who is the main contact?

Dr Fadil Hannan (scientific contact), [fadil.hannan@wrh.ox.ac.uk](mailto:fadil.hannan@wrh.ox.ac.uk)

## Contact information

### Type(s)

Principal investigator

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

272907

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 43843, IRAS 272907

## Study information

### Scientific Title

The NECTAR study: Evaluation of laboratory methods for measuring the composition of breastmilk

### Acronym

NECTAR

## **Study objectives**

**Aim:**

To establish laboratory tests for measuring the composition of human breast milk

**Outline of research:**

This study involves the collection of up to 10 ml of breast milk from up to 90 women who are already expressing milk for their babies in the Oxford Newborn Care Unit, Women's Centre, John Radcliffe Hospital, Oxford. The women are healthy volunteers and are recruited by virtue that their babies are NHS patients. The research milk samples will be used to evaluate the suitability of a range of laboratory tests for measuring hormones, cells, antibodies and metabolites in human milk. These laboratory tests will be used in future clinical studies to establish reference standards for key breast milk constituents, and to gain a greater understanding of how human milk influences the health and wellbeing of the breastfeeding infant.

**Justification:** Human breast milk is a nutrient-rich fluid, which additionally contains many factors with the potential to influence neonatal development, metabolism and health outcomes such as diabetes, obesity and neurodevelopment. However, little is known about the concentrations of these factors in human milk, and robust laboratory tests for measuring milk hormones have not been established.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 05/11/2019, West of Scotland REC 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley PA2 7DE; +44 (0)141-314-0212; WosRec1@ggc.scot.nhs.uk), ref: 19/WS/0174

## **Study design**

Observational; Design type: Validation of investigation /therapeutic procedures

## **Primary study design**

Observational

## **Study type(s)**

Other

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

Composition of breast milk

## **Interventions**

Study procedures:

1. Lactating mother to express 5-10 ml of breast milk into a sterile container
2. Milk sample transported to NDWRH laboratory for processing e.g. centrifugation
3. Processed milk sample analysed freshly or stored frozen for up to 3 months prior to analysis
4. Samples analysed in laboratories located in the University of Oxford or in OUHFT

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Ability to detect presence of hormones (e.g. insulin, leptin and parathyroid hormone related peptide), with samples analysed within 3 months of collection
2. Ability to detect presence of cells (e.g. mammary epithelial cells and immune cells), with samples analysed within 3 months of collection
3. Ability to detect presence of antibodies (e.g. immunoglobulin A), with samples analysed within 3 months of collection
4. Ability to detect presence of metabolites (e.g. breakdown products of bioactive substances such as serotonin), with samples analysed within 3 months of collection

**Key secondary outcome(s)**

-

**Completion date**

04/01/2024

## Eligibility

**Key inclusion criteria**

1. Female aged 18 to 45 years in established lactation and >1 week post-partum
2. Able to express breast milk by hand or using a pump device
3. Willing and able to give informed consent for this study
4. Able to understand and speak English

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

45 years

**Sex**

Female

**Key exclusion criteria**

Limited milk supply or not lactating for any reason

**Date of first enrolment**

01/03/2021

**Date of final enrolment**

04/01/2024

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**John Radcliffe Hospital**

Headley Way

Headington

United Kingdom

OX3 9DU

# Sponsor information

## Organisation

University of Oxford

# 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 and/or analysed during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V1.1	10/10/2019	18/02/2020	No	Yes
<a href="#">Protocol file</a>	version V1.1	10/10/2019	18/02/2020	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes