

Evaluation of laboratory methods for measuring the composition of breastmilk

Submission date 27/01/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/03/2023	Condition category 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

Study website

<https://www.ocehl.com/nectar>

Contact information

Type(s)

Principal Investigator

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

272907

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Laboratory method evaluation study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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Overall study start date

01/09/2019

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

Planned Sample Size: 90; UK Sample Size: 90

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**

England

United Kingdom

Study participating centre

John Radcliffe Hospital

Headley Way

Headington

United Kingdom

OX3 9DU

Sponsor information**Organisation**

University of Oxford

Sponsor details

University of Oxford Clinical Trials and Research Governance

Joint Research Office

1st Floor, Boundry Brook House

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Sponsor type

University/education

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 in a high-impact peer-reviewed journal.

Intention to publish date

31/03/2025

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?
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Participant information sheet	version V1.1	10/10/2019	18/02/2020	No	Yes
Protocol file	version V1.1	10/10/2019	18/02/2020	No	No
HRA research summary			28/06/2023	No	No