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Evaluation of laboratory methods for measuring the composition of breastmilk

Submission date	Recruitment status	[X] Prospectively registered
27/01/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/02/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2023	Nutritional, Metabolic, Endocrine	[_] 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 influences 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

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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
-

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?

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