Imaging of mammary lactation physiology

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53196

Source
ToetsingOnline

Brief title
View on lactation

Condition

- Other condition

Synonym
Breastfeeding physiology

Health condition

Borstvoeding

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ERC starting grant

Intervention

Keyword: Lactogenese, non-invasive, optics, physiology

Outcome measures

Primary outcome

The main study parameters are 1) the flow rate and total milk volume produced during one milk extraction with a breast pump and its relation to 2) the amount of glandular and adipose tissue inside the breast, and 3) the hemodynamics inside the breast, which will be studied by (changes in) the oxygen saturation and the available haemoglobin inside breast tissue.

Secondary outcome

The secondary outcome is the validation of DOSI with MRI for the measurement of the amount of glandular and adipose tissue inside the breast.

Study description

Background summary

Breastfeeding offers many benefits for mothers and children. Unfortunately, not every mother who wants to breastfeed, has the opportunity to feed her child herself. One of the most common reasons to stop breastfeeding is (the perception of) too little milk production, this is called lactation insufficiency. Until now, little is known about the causes of lactation insufficiency and the influence of the breast physiology on milk production.

Study objective

The aim of this study is to better understand the role of mammary lactation physiology and breast composition in regulating breast milk transfer during

milk extraction. The secondary aim is to validate the performance of diffuse optical spectroscopic imaging (DOSI) against magnetic resonance imaging (MRI) for this purpose. DOSI has the potential to be a more accessible and informative method for research into lactation physiology compared to other imaging modalities.

Study design

Observational

Study burden and risks

The test subject does not undergo any invasive, painful or harmful actions. The non-invasive DOSI measurements in this study are based on the use of low-power light. These DOSI measurements are painless, safe and do not affect the physiology of the breast. The DOSI probe is similar in size and design to an ultrasound probe. During the measurements, the DOSI probe is gently moved over the breast and scans a small surface with a laser beam. The load per subject is limited to a one-time measurement session that will take only about 1.5 to a maximum of 2 hours. The test subject determines the moment and day of the measurement session so that the natural course of breastfeeding is not disturbed.

The following measurements will be performed:
DOSI.
Before and after milk extraction with a breast pump, a DOSI scan of one entire breast is made. One measurement will take approximately 10 minutes, depending on the breast size. During the measurement, the subject lays still in a relaxed, supine position.
In addition, a continuous DOSI measurement is made at one location on the breast during milk extraction (lactating group) or a 10-minute period (non-lactating group).
MRI.
Before and after milk extraction with a breast pump, a MRI scan is made of the breasts. The MRI scan takes approximately 30 minutes.
No contrast agent is used for the MRI measurement, which makes the measurement non-invasive. All scans are made under the supervision of an experienced technician. During the measurement, the subject will lie in the MRI scanner for a maximum of 30 minutes.

All surfaces that are in contact with the subject during the DOSI and MRI measurement are sterilized before and after each measurement.
Participation in this study does not provide any direct benefit to the subjects. When the outcome of this study provides more insight into lactation physiology, mothers who experience lactation problems can potentially receive improved aid in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Group I
• Lactating women
• Between 18 to 45 years
• 0.5 to 12 months postpartum

Group II
• Non-lactating women
• Between 18 to 45 years
• >9 months postpartum of pregnancy
• >9 months post-breastfeeding of pregnancy

Exclusion criteria

Group I

• Breast augmentation, reduction, reconstruction or other procedures
• Breast tattoos or piercings
• Known breast disease at time of the experiment, e.g. mastitis
• Problems with breastfeeding at the time of experiment, e.g. mastitis
• Pregnancy
• Allergy for (medical) tape
• Not eligible for MRI, see F1. Vragenlijst Screening MRI. This includes having a:
• Pacemaker
• Implantable cardioverter-defibrillator (ICD)
• Hearing implant
• Drug pump
• Neurostimulator
• Claustrophobia

Group II
• Breast augmentation, reduction, reconstruction or other procedures
• Breast tattoos or piercings
• Known breast disease at time of the experiment
• Pregnancy
• Was pregnant or breastfeeding less than 9 months prior to moment of measurement (due to an expected difference in breast tissue composition)
• Allergy for (medical) tape
• Not eligible for MRI, see F1. Vragenlijst Screening MRI. This includes having a:
• Pacemaker
• Implantable cardioverter-defibrillator (ICD)
• Hearing implant
• Drug pump
• Neurostimulator

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Diffuse Optical Spectroscopic Imaging (Research Only)
Registration:	No

Ethics review

Approved WMO Date:	30-11-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84865.091.23