Monitoring the development of breast tissue composition during pregnancy, lactation and involution

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

Summary

ID

NL-OMON53278

Source
ToetsingOnline

Brief title
Breast development during pregnancy, lactation and beyond

Condition

- Other condition

Synonym
breastfeeding problems, lactation insufficiency

Health condition

Borstsamenstelling tijdens zwangerschap, lactatie en post-lactatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: involutie, Lactogenese, optics, physiology

Outcome measures

Primary outcome

This study aims to map the spatiotemporal changes in the anatomical and physiological parameters of the human lactating breast from pregnancy to post-lactational involution. The main study parameters are the amount of glandular and adipose tissue of the breast and the blood content of the breast, as well as a one-time 24h milk production measurement 4 to 6 weeks postpartum.

Secondary outcome

• Validate DOSI against MRI for measuring the amount of glandular and adipose tissue inside the breast

• Evaluate the relation between (changes in) breast tissue composition and milk production

• Define the duration of post-lactational involution

• Compare breast tissue composition before pregnancy to after post-lactational involution

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 how breast development during pregnancy and lactation influences milk production and breastfeeding duration. In addition, little is known about the changes in human breast anatomy during pregnancy, lactation and - in particular - post-lactational involution.
(Changes in) breast tissue composition during these periods affect the visualization of malignant lesions and may also affect the pharmacokinetics of chemotherapeutic agents. Also, an increasing amount of evidence indicates that the process of post-lactational involution in rodents is potentially related to the development of breast cancer. Therefore, more fundamental insight into human breast development during pregnancy, lactation and involution is of utmost importance.

Study objective

The aim of the study is to map the changes that occur in breast tissue composition during pregnancy, lactation and post-lactational involution. The secondary aims are to:
• validate the performance of diffuse optical spectroscopic imaging (DOSI) against magnetic resonance imaging (MRI) for this purpose. In previous pilot studies by the research team, DOSI has proven potential to be a more accessible and informative method for research into breast tissue composition compared to other imaging modalities, but it*s performance still needs to be assessed on a large scale.
• evaluate the relation between (changes in) breast tissue composition and milk production.
• define the duration of human post-lactational involution, which is currently unknown.
• compare breast tissue composition before pregnancy to after post-lactational involution.

Study design

A longitudinal observational study

Study burden and risks

The subject does not undergo any invasive, painful or harmful actions. No MRI scans will be performed during pregnancy. Participants decide themselves whether they breastfeed and for how long. That decision will not influence their participation.
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 following measurements will be performed:
• DOSI. A DOSI scan will be performed every six weeks from the end of the first trimester until 12 months after the stop of breastfeeding (or delivery, for non-breastfeeding participants). The measurement will take approximately 10 minutes, depending on the breast size. During the measurement, the subject lays still in a relaxed, supine position. Each measurement session takes approximately 30 minutes in total and is performed at a time and location of the subject's choice - for example, at their home.
• MRI. The subject will only be asked to come to the University of Twente for an additional MRI examination next to the DOSI scan on six occasions post-partum. This will be within 6 weeks post-partum and within 1, 3, 6, 9 and 12 months post-breastfeeding. The MRI scan takes approximately 45 minutes in addition to the DOSI scan time, so in total the measurement session will take a maximum of one hour and 15 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.
• Before pregnancy. Only if participants are included before pregnancy, one additional DOSI and MRI measurement are made before pregnancy.
• Milk production. For breastfeeding participants, milk production will be assessed at one time point, 4 to 6 weeks postpartum, with a 24h breastmilk production test weight method. The mother will weigh the infant before, and after feeding over a period of 24 hours and share these results with the research team. As an additional (indirect) indicator of milk production, we will ask the participants to share the growth curve of the infant as measured at the *consultatiebureau* by the *Gemeentelijke Gezondheidsdiensten* (GGD).

This research design minimizes the time burden for the subject. Depending on the duration of the breastfeeding period the time of the study is 2 to 3 years. Regardless of whether the participants still breastfeed their child, the study will come to an end in February 2027.
Participation in this study does not provide any direct benefit to the subjects, but it will aid in a more fundamental understanding of breast development during pregnancy, lactation and post-lactational involution. In the future, these insights can potentially contribute to a better understanding of the prevention and treatment of breastfeeding problems and breast cancer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

• Women with a child wish OR in the first trimester of pregnancy
• Between 18 to 45 years
• >9 months postpartum & post breast feeding of previous pregnancy

Exclusion criteria

• Breast augmentation, reduction, reconstruction or other procedures
• Breast tattoos or piercings
• Known breast disease at time of the experiment
• Pregnancy or breastfeeding < 9 months at the start of the study (due to differing breast physiology)
• 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2024
Enrollment:	10
Type:	Actual

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	NL84867.091.23