MRI pilot study of breastfeeding mothers with their babies

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The objective of this study is to better understand the forces and tongue movements that a baby uses while drinking at the breast and to what extent they contribute to effective feeding.

Ethical review	Not approved
Status	Will not start
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON35487

Source
ToetsingOnline

Brief title
MRI pilot study of breastfeeding mothers with their babies

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
breastfeeding(-problems)

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: Breastfeeding, Magnetic Resonance Imaging

Outcome measures

Primary outcome

The degree of displacement of various points on the tongue of the baby in time,

during breast feeding.

Secondary outcome

drinking behaviour of the baby in time (frequency of suckling motion,

irregularity etc.)

Study description

Background summary

The forces involved in the movement the baby*s mouth makes while the baby is drinking at the breast are not fully known. The baby uses underpressure to suckle milk from the breast, but he also uses his tongue to massage milk from the breast through a peristaltic motion. The extent to which both mechanisms contribute to the acquisition of milk are unknown.

Many lactating women also use a breast pump to express their milk. In this case, some of these women suffer from a delay or total absence of the for this process crucial milk ejection reflex, partly because the breast pump does not stimulate the nipple in an effective way. It is therefore important to develop a breast pump that does.

The most informative studies done in the field of the "mechanics" of breastfeeding have been performed by putting an ultrasound transducer under the chin of the breastfeeding baby to study the tongue motion of the baby. In this case however, the tip of the tongue cannot be visualized because of the presence of the mandible and imaging of the interface between tongue and nipple is limited by the use of ultrasound.

MRI can complement the limitations of ultrasound. By having MRI images of a breastfeeding baby, the understanding of breastfeeding increases, leading to the development of better breastfeeding products and better breastfeeding

advice. This in turn can lead to the prevention or resolution of breastfeeding-related problems, leading to prolonged breastfeeding, leading to improved health of mother and child.

Study objective

The objective of this study is to better understand the forces and tongue movements that a baby uses while drinking at the breast and to what extent they contribute to effective feeding.

Study design

This study is a non-therapeutic observational pilot study of healthy subjects.

Three mothers with their babies will be asked to breastfeed inside and MRI scanner. The mothers and babies will be lying on their sides, on top of a spinal MRI coil. While the baby is being breastfed, a time series of MRI images will be taken of the mid-sagittal plane of the baby's mouth surrounding the nipple of the mother.

Study burden and risks

The only burden and / or risks in this study are related to the method of MRI, which is generally accepted:

- There is a risk of disturbance of a breastfeeding session, since it takes place in unusual circumstances, namely in an MRI scanner which also makes noise, and because of the use of hearing protection for mother and baby, which may not be accepted by the baby.

- There is a risk of peripheral nerve stimulation of mother and baby, but this can largely be prevented by proper positioning of the baby and mother with respect to the coil that will be used.

Given the low number of babies that are breastfed, partly by misunderstanding and myth making about breastfeeding, while breastfeeding is proven to bring health benefits to mother and child, this scientific pilot study is justified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

healthy lactating women and their healthy term babies of 1-3 months old

Exclusion criteria

structural problems with breastfeeding
pregnancy
MRI-incompatible implants

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	15-04-2011
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL24472.015.09