The representation of the breast on the somatosensory cortex after autologous breast reconstruction using 7 Tesla functional MRI

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To study the neuroplasticity of the brain after mastectomy and breast reconstructive surgery by assessing the somatotopy of the breast on the somatosensory cortex of patients who underwent either breast reconstruction with and without nerve...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON56123

Source
ToetsingOnline

Brief title
fMRI study reconstructed breasts

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
Sensation of the breast, sensibility of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast, Magnetic Resonance Imaging, Somatosensory cortex

Outcome measures

Primary outcome

The hemodynamic response after stimulation of the skin of the breast and nipple-areola complex, representing neuronal activity in that region, is measured. Within the somatosensory cortex (S1 and S2), the temporo-spatial brain activity patterns after the various stimulation conditions are assessed, and the representation of the breast on the somatosensory cortex is mapped.

Secondary outcome

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Study description

Background summary

To study the effects of mastectomy and autologous breast reconstruction on the sensation of the (reconstructed) breast, not only the peripheral reinnervation of the breast should be studied, but also the changes that take place in the somatosensory cortex. The sensation of the reconstructed breast has been studied previously, but the neuroplasticity of the brain, or the ability of the brain to change after - in this case - breast surgery, remains unknown. Recently, a pilot study with healthy subjects has been conducted to localize the sensation of the breast on the somatosensory cortex using 7 Tesla functional MRI imaging. Now that the region of interest in the brain and the somatotopy of the non-operated breast are known, studies with patients who underwent mastectomy and breast reconstruction are the next step to understand the neuroplasticity of the brain following breast surgery.

Study objective

To study the neuroplasticity of the brain after mastectomy and breast reconstructive surgery by assessing the somatotopy of the breast on the somatosensory cortex of patients who underwent either breast reconstruction with and without nerve restoration or mastectomy without breast reconstruction.

Study design

A single center imaging study carried out in MUMC+. Every subject will undergo a single functional MRI scan in the 7 Tesla MRI scan of Scannexus at least six months after the operation. A scanning session takes approximately 75 minutes. During the scan, piezo-electric stimulators are applied to both the reconstructed and non-operated breast in a fixed pattern. These stimulators stimulate the skin and sensory nerves of the breast and nipple-areola complex in a random sequence.

Study burden and risks

All subjects are recruited by their treating physicians at the outpatient clinic of plastic surgery and surgical oncology or by means of a recruitment letter on behalf of the treating physician. Patients are informed about the study and the procedures, and the subject information and consent form are handed out. If patients are willing to participate, an appointment is made with the researcher to sign the consent form, fill out the CRF and schedule the MRI scan. On a later moment every subject will undergo a single functional MRI scan taking 75 minutes. There are no follow-up moments. Subjects do not have any direct benefits in participating in the study. In the rare case an anomaly is identified on any of the fMRI images, this will be discussed with the subject and this information is shared with the general practitioner. Subjects who are willing to participate in the study, accept the fact that stimulators are applied on a bare breast to stimulate the skin and nipple-areola complex. The burden associated with participation in this study, involves the usual MRI side effects (e.g. anxious or claustrophobic feelings) and a possible adverse skin reaction to adhesives upon applying the stimulators. No radiation is involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Female over 18 years old
- Unilateral mastectomy without breast reconstruction
- Unilateral mastectomy with DIEP flap breast reconstruction (with or without sensory nerve restoration)
- At least six months after initial surgery
- Informed consent

Exclusion criteria

- Bilateral mastectomy / breast reconstruction
- Active disease / metastasis
- Previous radiation therapy on the breast or axilla
- Diseases associated with neuropathy (e.g. diabetes mellitus)
- Previous brain surgery
- Previous allergic reactions to adhesives or plasters
- Any MRI exclusion criteria:
-- No piercings or other iron materials (except a metal brace behind front teeth)
--Pacemaker/ICD, implanted pumps or stimulators
-- Claustrophobia

-- Epilepsy
-- Heart rhythm disorders
-- Pregnancy
-- Permanent make-up or tattoos in head and neck area

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT03702556
CCMO	NL67696.068.18