The effect of explantation of silicone breast implants on neuroimages of the brain in ASIA-syndrome patients: a pilot fMRI-study

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To investigate the effect of explantation of silicone breast implants on neuroimaging of the brain (fMRI) in ASIA syndrome patients to gain more insight in the neurophysiological basis and nociceptive system of ASIA syndrome due to SIIS and the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Therapeutic and nontherapeutic effects (excl toxicity)
Study type	Interventional

Summary

ID

NL-OMON45422

Source
ToetsingOnline

Brief title
The effect of explantation of SBI on fMRI

Condition

- Therapeutic and nontherapeutic effects (excl toxicity)
- Structural brain disorders

Synonym
ASIA-syndrome due to SIIS

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: ASIA-syndrome, Explantation, fMRI, Silicone breast implants

Outcome measures

Primary outcome

1) Blood oxygenation level dependent (BOLD) respons (fMRI): a) during tactile

stimulation, b) at rest;

2) Fractional anisotropy (FA) of water diffusivity;

3) Tactile discrimination thresholds in mm.

Secondary outcome

4) The presence of complaints defined as the typical ASIA manifestations (the

2010 ACR-criteria for fibromyalgia);

5) Pain scores (Visual Analog Scale; VAS 0-10);

6) Pain-related fear (Tampa Scale for Kinesiophobia and/or PASS-20);

7) Catastrophic thinking (Pain Catastrophizing Scale; PCS);

8) Baseline characteristics: gender, age, cultural background, marital status,

level of education, profession, work situation.

Study description

Background summary

In 2011, Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA-syndrome) is first described. ASIA-syndrome is a clinical diagnosis with a variety of clinical manifestations such as fatigue, sleep disturbances, cognitive

impairment (e.g. concentrating problems and/or memory loss), but also TIA/CVA-like complaints have been described. These complaints are possible due to 'Silicone Implant Incompatibility Syndrome' (SIIS). The symptoms observed in ASIA mimic the symptoms of fibromyalgia. Interestingly, however we and others have documented improvement of symptoms and signs after explantation of the silicone breast Implants in 50-70% of the patients.
This study aims to investigate the effect of explantation of silicone breast implants on brain regions involved in the processing of harmless tactile stimuli in ASIA syndrome patients due to SIIS, with the purpose to reduce or disappear ASIA syndrome related complaints. This will be the first study to perform functional MRI scans in ASIA syndrome patients.

Study objective

To investigate the effect of explantation of silicone breast implants on neuroimaging of the brain (fMRI) in ASIA syndrome patients to gain more insight in the neurophysiological basis and nociceptive system of ASIA syndrome due to SIIS and the effect on ASIA complaints.

Study design

This study will be a monocenter exploratory pilot functional MRI study carried out in the Maastricht University Medical Center (MUMC+).

Intervention

All subjects will undergo an fMRI scan, from which the 4 ASIA syndrome patients will undergo a fMRI scan twice (pre- and post-explantation).

Study burden and risks

All patients (group 1 and group 2) will undergo two sessions: a diagnostic session and an functional MRI session, which each will take 1.5 hour of their time (excl. traveling costs). In total 3 hours will be taken. For the ASIA syndrome patients this will be 6 hours, because they will undergo the 2 sessions twice (pre- and postexplantation).

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

ASIA-patients (group 1):
- Gender: female adults
- Age: 25 to 76 years old
- Diagnosis of ASIA-syndrome
- No diagnosis of a chronic pain syndrome, fibromyalgia (FM) or chronic fatigue syndrome (CFS)).
- Silicone filled breast implants
- Cosmetic purpose of silicone breast implants
- Cognitive impairment and/or memory disturbances;Healthy control patients (group 2):
- Gender: female adults
- Matched for gender and implant duration
- Healthy (no diagnosis of ASIA-syndrome, a chronic pain syndrome, fibromyalgia (FM) or chronic fatigue syndrome (CFS))
- Silicone filled breast implants
- Cosmetic purpose of silicone breast implants
- No complaints of cognitive impairment and/or memory disturbances

Exclusion criteria

ASIA-patients (group 1):
- Pregnancy
- Cancer
- Diabetes Mellitus
- Claustrophobia or fear of being in a closed space
- Neuropathy of the upper or lower extremities
- Medication: antidepressants, any analgesics, anticonvulsants, muscle relaxants or benzodiazepines
- MRI incompatible health condition (i.e., ICD, pacemaker or other metal prosthetic implants)
- Neurological manifestations (CVA/TIA-like complaints);Healthy control patients (group 2):
- Pregnancy
- Cancer
- Diabetes Mellitus
- Medication: antidepressants, any analgesics, anticonvulsants, muscle relaxants or benzodiazepines
- MRI incompatible health condition (i.e., ICD, pacemaker or other metal prosthetic implants)
- Neurological manifestations (CVA/TIA-like complaints)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	9
Type:	Anticipated

Ethics review

Approved WMO Date:	11-10-2017
Application type:	First submission
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
CCMO	NL59074.068.16