Inamed 410 Silicon-Filled Breast Implant European MRI-Study

Published: 02-11-2007
Last updated: 08-05-2024

proof of safety of the Style 410 silicon breast implants

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON30753

Source
ToetsingOnline

Brief title
Inamed 410 Silicon-Filled Breast Implant European MRI-Study

Condition

- Breast therapeutic procedures

Synonym
breastimplants

Research involving
Human

Sponsors and support

Primary sponsor: Allergan Medical
Source(s) of monetary or material Support: fabrikant

Intervention

Keyword: breast-implant, silicone

Outcome measures

Primary outcome

n.a.

Secondary outcome

n.a.

Study description

Background summary

control of the integrity of Style 410 silicon breast implants

Study objective

proof of safety of the Style 410 silicon breast implants

Study design

patients with Style 410 silicon breast implants implanted between 1995 and 1999
get both a physical and MRI check of the breasts.

Study burden and risks

none

Contacts

Public
Allergan Medical

146 Impasse du Pont
30000 Nimes
Frankrijk
Scientific
Allergan Medical

146 Impasse du Pont

30000 Nimes
Frankrijk

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

women who were implanted in 1995-1999 with McGan Medical Silicone-Filled breast omplants Styles 410 and still have at least one of those original implants
patients must be willing to undergo a MRI-scan. Patients must be eligible for MRI
Patients must hcommit to following study requirements and must have signed and dated the Informed Consent prior to any study procedures being performed

Exclusion criteria

patient is pregnant or nursing
patient has any type of implanted material or metal devices that may make her ineligible for MRI
patient has a history of severe claustrophobia that may make her ineligible for MRI
patient only had other implants that McGhan Style 410

Study design

Design

Study phase:	4
Study type:	Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-11-2007
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL15984.094.07