Galectin-1 and -3 as biomarkers for capsular contracture. A pilot study

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

Summary

ID

NL-OMON44974

Source
ToetsingOnline

Brief title
Galectin-1 and -3 as biomarkers for capsular contracture

Condition

- Breast therapeutic procedures

Synonym
capsular contracture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomarker, capsular contracture, implant

Outcome measures

Primary outcome

Serum and local Galectin-1, -3, HLA and IgE

Secondary outcome

Not applicable.

Study description

Background summary

Silicone implants have been used in breast augmentation mammoplasty and in reconstruction following mastectomy. Capsular contracture is the most common complication and most frequent cause for reoperation after implant placement. To date, the cause of capsular contracture is unknown. One of the etiologic pathways described in literature is low-grade chronic inflammation caused by a foreign-body reaction or low-grade infection. Furthermore, it has been recently suggested that there is an association between local and systemic complications. Therefore, the severity of capsular contracture may be used as a diagnostic marker to identify unexplained systemic complications probably related to silicone. Currently, local complications are objectified through physical examination and graded by the Baker scale. The Baker grading is an esthetic outcome measurement, but does not provide information on the extent of fibrosis around silicone implants. Association between the biomarker Galectin-3 levels and various types of fibrosis has been demonstrated recently in the literature. We therefore postulate, since the pathogenesis of capsular contracture may be quite similar to that of other fibrotic disorders, that Galectin-3 can be objectively used as a biomarker to assess the severity of capsular contracture in patients with silicone implants. Moreover, Galectin-1 has been found in angiogenetic processes in the body, which might be similar to capsular contracture. Therefore, we suggest that Galectin-1 can indicate the degree of fibrosis in capsules around breast implants. Moreover, foreign-body mediators such as Human Leucocyte Antigen (HLA) and Immunoglubulin E (IgE) may provide important information on genetic susceptibility and atopic constitution which may enhance the chance to develop capsular contracture.

Study objective

The aim of this study is to identify Galectin-1 and -3 as possible biomarkers in capsular contracture. Moreover, we plan to investigate whether HLA-typing and IgE levels in subjects can be used to predict the chance of development of capsular contracture in the future

Study design

The study is a cross-sectional pilot study

Study burden and risks

There is no risk involved in participation and the burden associated with participation is very small. One venous blood sample will be collected as well as the breast capsule which will be removed during surgery. All participants will be asked to fill in a short questionnaire about capsular contracture. Background and clinical data is acquired by retrospective analysis of the patient files. Participants will be informed about the purpose of this research and are free to refuse participation.

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

- females aged 18 or over
- females who have developed capsular contracture (Baker score 1&2 and 3&4) after bilateral cosmetic breast augmentation with silicone breast implants at least one year after implant implantation
- females who who are on the waiting list for a breast augmentation will serve as a control group

Exclusion criteria

- females who have a co-morbidity (e.g. diseases of the liver, lung, heart, kidney, or skin);
- females who have (a history of) cancer
- females who have a capsular contracture for more than 5 years
- females who have had silicone injections
- females who are currently smoking or smoked in the past year

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	29-08-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50729.029.14