Breast reconstruction: differences in outcome between two types of breast implants?

Gepubliceerd: 09-06-2018 Laatst bijgewerkt: 18-08-2022

Two-stage implant-based breast reconstruction is the most common reconstructive technique after mastectomy. It is associated with some implant specific complications such as capsular contracture. Capsular contracture is one of the most frequent long…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29142

Bron
Nationaal Trial Register

Verkorte titel
TIPI Trail

Aandoening

Breast reconstruction; breast implants; capsular contracture

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: POLYTECH Health & Aesthetics B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

capsular contracture rate

Toelichting onderzoek

Doel van het onderzoek

Two-stage implant-based breast reconstruction is the most common reconstructive technique after mastectomy. It is associated with some implant specific complications such as capsular contracture. Capsular contracture is one of the most frequent long-term complications which develops when the capsule surrounding the implant, which always develops as a result of a normal foreign body reaction, becomes constricted and tight, resulting in malposition of the implant, a firm and/or painful breast and deterioration of the aesthetic result, which may require reoperation. On average one out of every six implant breast reconstruction patients will develop a capsular contracture after 10 years. Much of the etiology is still unknown, but a relationship between the outer surface of the implant and the chance of developing capsular contracture has been suggested . For example, compared to smooth implants, textured implants have shown to result in lower capsular contracture rates. Based on the current literature, which comprises of retrospective cohort studies and case-series, we hypothesize that polyurethane-covered implants reduce or delay the development of capsular contracture compared to textured implants.

Onderzoeksopzet

Surgery - 2 weeks post-op - 6 months post-op - yearly from 1 year post-op until 10 years post-op.

Onderzoeksproduct en/of interventie

Patients in both cohorts will receive a two-stage implant-based breast reconstruction after mastectomy. In the second stage, the intervention cohort will receive a polyurethane covered silicone implant and the control cohort will receive a standard textured silicone implant.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Female

• Age of 18 years or older

• Mastectomy is performed

• Eligible for two-stage implant-based breast reconstruction in accordance with the Dutch national breast reconstruction guideline

• First step of two-stage implant-based breast reconstruction (placement of tissue expander) is successfully completed

• Able to understand the patient information sheet, to complete questionnaires and to provide written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Additional use of autologous tissues for the breast reconstruction

• The use of acellular dermal matrix or synthetic mesh

• Prior irradiation of the breast or an indication for postoperative radiotherapy

• Revision surgery or tertiary breast reconstruction

• Inflammatory carcinoma

• Evidence of distant metastases

• Active infection at the surgical field or distant locations

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-02-2019
Aantal proefpersonen:	321
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7067
NTR-old	NTR7265
Ander register	63959 : ABR

Resultaten