Effects of discharge with a surgical drain in place on the risk of infection after placement of a tissue expander

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Patients can be discharged, after a post-mastectomy reconstruction with a tissue expander, with a surgical drain in situ without an increase in the removal of tissue expanders due to infection.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28105

Bron
Nationaal Trial Register

Aandoening

Infection, Tissue Expander, Surgical drain, Breastreconstruction

Ondersteuning

Primaire sponsor: Martini Ziekenhuis Groningen
Overige ondersteuning: Martini Ziekenhuis Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter is the percentage of removed tissue expanders due to infection.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a randomised control trial to assess if patients can be discharged homewards with a surgical drain in situ, after reconstruction with a tissue-expander post-mastectomy, without an increase in removal of tissue expanders due to infection.

There will be two groups. One will receive care as usual and will be discharged after removal of the drain (on the 7th post-operative day at the latest)
The other group will be discharged on the 3th post-operative day with drains in situ after receiving instructions on drain-care.

The percentages of removal of tissue-expanders due to infection and antibiotics usage due to infection will be registered and compared.

Doel van het onderzoek

Patients can be discharged, after a post-mastectomy reconstruction with a tissue expander, with a surgical drain in situ without an increase in the removal of tissue expanders due to infection.

Onderzoeksopzet

Outcome: percentage of patients in which the tissue expander had to be removed due to infection, timepoint: within 21 days after the surgery.

Outcome: percentage of patients receiving AB due to infection, timepoint: within 21 days after the surgery.

Onderzoeksproduct en/of interventie

This study divides the subjects into two groups. The first group will receive care as usual, in which the patients will stay in the hospital until the drain is removed. (on the 7th postoperative day at the latest) The second group will be discharged on the 3rd postoperative day with a surgical drain in situ after receiving instructions on how to take care of the drain.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women >18 years with a post-mastectomy reconstruction with a tissue expander

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Insufficient self-care, the inability to be sufficiently instructed on how to care for the drain. (aliteracy, language-barrier, mental retardation, psychiatric disorders)

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50301
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6749
NTR-old	NTR6927
CCMO	NL64530.099.17
OMON	NL-OMON50301

Resultaten