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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28105

Source
Nationaal Trial Register

Health condition

Infection, Tissue Expander, Surgical drain, Breastreconstruction

Sponsors and support

Primary sponsor: Martini Ziekenhuis Groningen
Source(s) of monetary or material Support: Martini Ziekenhuis Groningen

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary study parameter is the percentage of patients who get a prescription for

antibiotics due to infection (IV or/and oral antibiotics).

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Department of plastic surgery, Martini Ziekenhuis Groningen

SJM Jongen
Van Swietenplein 1

Groningen 9728 NT
The Netherlands
Scientific
Department of plastic surgery, Martini Ziekenhuis Groningen

SJM Jongen
Van Swietenplein 1

Groningen 9728 NT
The Netherlands

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50301
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results