Effects of discharge with drain in situ on the risk of infection after placement of a tissue expander.

Published: 05-06-2018
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The primary objective of the study is to objective if there is a greater risk of loss of the tissue expander due to infection if patients are discharged with a surgical drain in situ.

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

Summary

ID

NL-OMON50301

Source
ToetsingOnline

Brief title
Effects of discharge with drain in situ on the risk of infection

Condition

- Breast therapeutic procedures

Synonym
Early discharge with a surgical drain in place, Early discharge with surgical drain in situ

Research involving
Human

Sponsors and support

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

Intervention

Keyword: - Discharge, - Infection rate, - Surgical drain, - Tissue Expander

Outcome measures

Primary outcome

The primary study parameter is the percentage of removed tissue expander 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

All women undergoing a mastectomy with reconstruction by tissue expander or final prothesis have a surgical drain postoperatively. The drain is removed on the 7th postoperative day or if the drain produces less than 30ml per 24 hours. Patients will often make a rapid recovery and most are ready for discharge within a few days, which means they will have to remain in the hospital until the drain can be removed. Caring for a drain is a simple procedure which can be performed by the patient if they receive a thorough instruction. Discharging patients with a drain in situ could potentially reduce the duration of hospital stay considerably.

Study objective

The primary objective of the study is to objective if there is a greater risk of loss of the tissue expander due to infection if patients are discharged with a surgical drain in situ.

Study design

This study is a prospective randomized control-trial. 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. They will receive written and verbal instruction, on how to take care of the drain, prior to discharge. Patients will have an additional check-up in an outpatient unit on the 5th postoperative day. On the 7th postoperative day the patients always have an appointment with the surgeon to discuss the results of the pathology report, this appointment will combined with the appointment for removing the drain. Patients are instructed to make an appointment for removal of the drain if it produces less than 30ml in 24 hours before the 7th day.

Study burden and risks

Patients that are discharged with a drain in situ will have a minimum of 1 (for wound inspection on the 5th postoperative day) and a maximum of 2 additional appointments (an additional visit to remove the surgical drain before the 7th post-operative day) in comparison to patients receiving the regular treatment. These additional visits and clear instructions on how to take care of the drain will reduce the possibility of an increased risk of infection, by participating in this study, to a minimum. Patients will still receive the same treatment, but just in another location (home).

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

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 disease)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2018
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	05-06-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	09-03-2020
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28105
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	28365
CCMO	NL64530.099.17
OMON	NL-OMON28105