Aquacel AG Surgical trial: reducing wound infections after breast cancer surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24162

Source
Nationaal Trial Register

Health condition

breast cancer
surgery
wound infection
silver containing dressing
patient satisfaction

Mammacarcinoom
chirurgie
wondinfectie
zilververband
patienttevredenheid

Sponsors and support

Primary sponsor: Franciscus Gasthuis&Vlietland
Source(s) of monetary or material Support: Convatec

Intervention

Outcome measures

Primary outcome

Primary outcome of this study was incidence of post-operative wound infection, following CDC criteria

Secondary outcome

Secondary outcome measure was patient satisfaction on a 10-point numerical rating scale, presence of 2 'classic' symptoms of infectionsre-admissions/operations, infections and use of antibiotics

Study description

Study objective

One out of eight women will develop breast cancer, the majority of this group receives breast surgery. Each clinic has its own ‘standard’ postoperative wound care. Standard wound dressings can have undesirable side effects, like wound infections and blister formation, for example by changing the dressing on regular base. This study compares Aquacel AG Surgical with standard wound dressing. This occlusive dressing delivers ionic silver when in contact with the wound exudate and has an antibacterial effect, which makes less changing of the dressing needed. In our hospital infection rate after breast cancer surgery is 12-13%, several studies in literature mention 3-15%. Main goal of this study is to determine if the use of Aquacel AG Surgical reduces the occurrence of postoperative wound infections after breast cancer surgery.

Study design

see interventions

Intervention

Included patients underwent breast surgery; breast ablative therapy or breast conservative therapy. All procedures were performed or supervised by senior surgeons with a case load of more than 50 per year. After surgery, patients got their allocated wound care: standard wound dressing, consisting of a gauze fixed with adhesive tape, or Aquacel Ag Surgical. Standard wound dressing was changed as often as needed, in patients opinion . Aquacel Ag Surgical was kept in place for 7 days, unless saturated by excessive exudate . After the 10th day of surgery, follow up took place at the outpatient clinic by an independent specialized nurse and the surgeon or surgical resident. The wound was inspected on the presence of infection following CDC criteria and patients filled out a questionnaire on patient satisfaction.

Re-admissions/operations, extra ER /GP/outpatient clinic visits, the occurrence wound infections and use of antibiotics were scored 30 days after surgery during a phone consult. Patient records were checked for deep infections until the 90th day post-operative.

Contacts

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Eligibility criteria

Inclusion criteria

women of 18 years or older

diagnosed with breast cancer,

needing ablative or breast conserving surgery

written informed consent.

Exclusion criteria

local inflammation or ulceration of the breast;

prior breast surgery in the past 3 months;

use of antibiotics in the past 2 weeks;

neo-adjuvant chemotherapy;

direct reconstruction

known allergy for Aquacel AG Surgical or silver

inability of reading or understanding to give informed consent or fill out questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2013
Enrollment:	212
Type:	Actual

Ethics review

Positive opinion

Date:	26-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38445
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5601
NTR-old	NTR5840
CCMO	NL42892.101.12
OMON	NL-OMON38445

Study results