Aquacel Ag Surgical in breast cancer study

Published: 27-03-2013
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Primary research question:Will the use of Aquacel Ag Surgical as a postoperative wound dressing result in less postoperative wound infections?

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38445

Source
ToetsingOnline

Brief title
Aquacel Ag Surgical Study

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
wound infections

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Bedrijf: Convatec ,Convatec

Intervention

Keyword: Aquacel Ag Surgical, Post operative wound infection, Wound dressing

Outcome measures

Primary outcome

The hypothesis is that Aquacel Ag Surgical will result in a lower rate of

postoperative wound infections because of the silver coating.

Secondary outcome

none

Study description

Background summary

Breast cancer has a high incidence among women. Almost every woman diagnosed with breast cancer should undergo surgery (breast ablative surgery or breast conserving surgery).
There is no consensus about the best choice for wound dressing after breast cancer surgery.
Aquacel Ag Surgical is a fluid absorbing material with a silver coating. The absorption of wound exsudate will result in a dry woud with no need for frequent renewal of the wound dressing. The silvercoating should result in less postoperative wound infections.

Aquacel Ag Surgical is mainly used as a wound dressing in orthopedic surgery. In orthopedic surgery Aquacel Ag Surgical has proven to reduce postoperative wound infections.

The hypothesis is that Aquacel Ag Surgical will reduce postoperative wound infections because of the silver coating.

Study objective

Primary research question:

Will the use of Aquacel Ag Surgical as a postoperative wound dressing result in less postoperative wound infections?

Study design

Randomized Controlled Trial, non blinded.

Patients will be randomized in two groups: standard wound dressing or Aquacel Ag Surgical

Stratification is performed for the following criteria:

• Age (younger than 60 years versus 60 years and older)
• Axillary node dissection (yes / no)
• Diabetes (yes / no)
• Use of corticosteroids (yes / no)
• Operation (lumpectomy versus ablation)

Intervention

The use of Aquacel Ag Surgical instead of a gauze and tape

Study burden and risks

The risks are nihil (possible allergies for the wound dressing)

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 diagnosed with breast cancer who will undergo breast surgery (ablative therapy or breast conserving therapy)

Exclusion criteria

-local inflammation or ulceration of the breast
-use of antibiotics 2 weeks prior to surgery
-prior breast surgery past 3 months
-allergy for Aquacel Ag Surgical
-the inability of reading/understanding not enabling to give informed consent or to fill out questionnaires

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-03-2013
Enrollment:	212

Type:	Anticipated

Ethics review

Approved WMO Date:	27-03-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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: 24162
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42892.101.12
OMON	NL-OMON24162