Wound treatment in orthopedic surgery; a prospective randomised study of Aquacel Surgical versus Curapor after total knee and total hip surgey.

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This research aims to conduct blistering and reduce freguent dressing changes in patients undergoing total hip replacement or total knee replacement have undergone in the use of Aquacel Surgical dressing.This compares with the usual method of wound...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON38224

Source
ToetsingOnline

Brief title
Aquacel Surgical versus Curapor after total hip and total knee surgery

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Wound healing and blistering.

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Het Deventer Ziekenhuis.

Intervention

Keyword: Blistering, Change dressing

Outcome measures

Primary outcome

It is expected that test subjects who make use of Aquacel Surgical connection,

less blistering will develop.

Research Variables that we will include it in the study are:

ASA .

Gender.

Test Persons prednisolone use.

People who are diabetic test.

Test Persons who use oral anticoagulation (Sintrom, warfarin, plavix, press

Antin, Ascal) or therapeutic dose fraxiparine.

BMI.

SNAQ score.

Antibiotics postoperatively.

Secondary outcome

Less dressing changes.

Patient satisfaction.

Satisfaction of nurses.

Time of hospital admission

VAS score

Study description

Background summary

From figures from the database Deventer Hospital, Department of Orthopedics, that stores information on all patients in the last 6 years a total hip replacement or total knee replacement processes is shown that 20% of 600 patients each year a new total hip prosthesis or total knee replacement has been wound leakage or blistering has occurred. This wound leakage was still there afther the expected date of discharge.This is reason for us to start an investigation to see if a new dressing material herein will have a positive effect. To date, all patients postoperatively treated with respect curapor.
This is under sterile conditions applied to the operating room. In the course of the recording, the patient daily vliwazell absorbent dressing or curapor related to the surgical site. Experience has shown that frequent dressing changes are necessary due to wound leakage, both blood and wound fluid. Particularly when removing the patch / relationships between the edematous skin blistering occurs.

Study objective

This research aims to conduct blistering and reduce freguent dressing changes in patients undergoing total hip replacement or total knee replacement have undergone in the use of Aquacel Surgical dressing.
This compares with the usual method of wound postoperatively. First curapor the link that normally is applied postoperatively after which change over to vliwazell absorbent dressing, Aquacel Surgical other new context which is applied postoperatively and normally 4 days postoperatively, until the day of discharge remains in place. It also will show whether the use of Aquacel Surgical hospitalization was not any extension will occur.

Study design

Base population, 600 elective hip and knee operations in 2010.
200 subjects with 100 test subjects Aquacel Surgical connection and started using 100 test subjects curapor keep using it.
50 test subjects that an elective total hip replacement and 50 test persons who have an elective total knee replacement, on the operating room with a Aquacel Surgical plaster on the wound.
50 test subjects that an elective total hip replacement and 50 test persons who

have an elective total knee replacement, on the operating room with a curapor plaster on the wound.
The Aquacel Surgical patch will remain there until dismissal. If serious leakage is wound, the bandage is replaced.
Curapor the patch will be removed 24 hours postoperatively and replaced by vliwazell 10x20 cm. Depending on the wound will spill absorbent dressing at least once a day to be replaced.

Intervention

The research is conducted with patients admitted to the ward the following specialty: Orthopedics. The study will be a period of 6-12 months and take place in 2012.
The control group consisting of 100 test persons; 50 elective total hip arthroplasty and 50 elective total knee replacements will receive a curapor link during OK. 24 hours after that it will be replaced by vliwazell 10x20 cm. with leukopor. It depents on the woundlekage if dressing change is nessesary. If extreme woundlekage occured than we all so use a celstofmatje 40x60 cm. This belongs to the standard of woundcare.
100 Test Persons; 50 elective total hip arthroplasty and 50 elective total knee replacements will receive a one time Surgical dressing Aquacel OK to dismissal.
The treatment effect is measured through the so-called product evaluation forms to be completed after each dressing change.

Study burden and risks

All test subjects have to complete the evaluation form at the first and third day after surgery.

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

All elective performed surgery of total hip protheses and total knie prostheses during the study period.

Exclusion criteria

Patients with specific skin allergy to Aquacel Surgical
All minors and patients incapabel of giving informed consent
Patients unfamiliar with the dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2012
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Aquacel Surgical wound treatment
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-08-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL35789.075.11