Aquacel Surgical ® ' versus ' Mepilex Border Post on ® ' in patients with elective total knee prosthesis (TKP)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44616

Source
ToetsingOnline

Brief title
nvt

Condition

- Other condition
- Joint disorders

Synonym
total knee arthroplasty, wounddressing

Health condition

wondverzorging

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: eigen stimuleringsfonds,Molnycke healthcare (leveren wondverband)

Intervention

Keyword: total knee arthroplasty, wounddressing

Outcome measures

Primary outcome

The primary endpoint is whether or not to replace the wounddressing during

hospitalization.

Secondary outcome

- Postoperative blistering

- skin problems, (blistering, Erythema, skin damage, haematoom).

- detachement during showering,

- pain when removing the wounddressing using a 7 point likert scale

- ease of use when removing the wounddressing using a 7 point likert scale

Study description

Background summary

At the Department of Orthopaedics of the Spaarne Ziekenhuis annually 350 patients with gonarthrosis are operated on by means of placement of a total knee prosthesis (TKP).
These patients are treated according to the Fast-Track protocol. The Fast-Track clinical pathway is a multimodal, multidisciplinary concept. Patients with total knee prosthesis will be mobilized a few hours after the operation. If patients are mobilized quickly after surgery, the probability of complication is even less and the will recover faster. Experience shows that the length of the patients with total knee prosthesis is reduced by the Fast-Track protocol.

One of the risks of this surgery is a surgical site infection (SSI). To minimize this risk we work in accordance with the national guidelines of the Working Group Prevention(WIP) and PREZIES(prevention of hospital infections by Surveillance). In addition to these national guidelines the Spaarne hospital also has internal measures in place to reduce the risk of SSI. The postoperative use of a wound drain is abolished and a pressure bandage will be applied for 24 hours instead of 48 hours. After removing the pressure bandage the wound is covered with a wounddressing.

Untill 2009 blisters were regularly observed around the wound after a TKP and THP. Blisters are formed in the epidermis bordering the surgical incision of the wound and are a major cause of discomfort, pain and postoperative morbidity and can result in prolonged hospital stay and even infection of the prothesis
At the time ' Curapor bandage material® ' was used in combination with a pressure bandage. To examine if the related material was an influence on the prevalence of blistering, from november 2009 until March 2010 a comparative study was conducted involving ' Curapor ® ' and Aquacel ®, in combination with a foil tegaderm bandage. This investigation showed when using Aquacel ® in combination with the tegaderm occurrence of blistering and the number of related changes were significantly less and satisfaction of using Aquacel ® among both patients and nurses better (not published). Following the results of the research in september 2010 it was decided to use the Aquacel Surgical ® at the follow-up treatment of TKP and THP operations.

The current dressing meets the clinical requirements, but has high costs. In 2007, Mepilex Border Post op ® was introduced for use in postoperative wounds. This bandage material has also shown that it is more effective than Curapor. Mepilex Border Post op ® is already used in prosthetics in other hospitals and is cheaper than the Aquacel Surgical ®. However, a comparative study of the effectiveness of these related materials has not yet taken place.
The aim of this study is to evaluate whether Mepilex Border Post op is at least as effective as the Aquacel ® Surgical ® in terms of blistering, number of dressing and satisfaction of both the patient and the nurse.

Study objective

The primary goal of this non-inferiority study is to show that the Mepilex Border Post op does not perform worse than the Aquacel ® Surgical ® regarding replacing the wounddressing during hospitalization in patients with TKP.
In other words; the Mepilex Border Post op ® is just as often or less often replaced during hospitalization compared to the Aquacel Surgical ® in patients with elective TKP. Since there is rarely more than one exchange of the wounddressing during hospitalization, the primary outcome measure will be how many times the wounddressing will be replaced during hospitalization.

Study design

These non-inferiority study concerns a single-center, open-label, randomized controlled intervention study in order to assess whether the Mepilex Border Post op is at least equivalent to the Aquacel Surgical ® (reference treatment) in patients with TKP.

Intervention

Subjects can be randomized in one of the following two groups:
- wound dressing Aquacel Surgical or
-wound dressing Mepilex Border post op

Study burden and risks

One follow-up visit at the outpatient clinic to remove the sutures is seen as a minimum load for the participants. This is only necessary if there is any wound leakage at dismissal. This is a standard treatment

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

- elective TKA
- primary gonarthrosis
- patients are mentally and psychologically able to give permission
- written informed consent
- 18 years or older
- patients are able to understand the Dutch language
- ASA 1 or 2
-patient should be able to participate in the follow-up program
- no allergy for one of the wounddressings

Exclusion criteria

- ASA 3-4
- usage of a wounddrain
- corticosteroid use
- Diabetes Mellitus

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	28-04-2015
Enrollment:	246
Type:	Actual

Ethics review

Approved WMO Date:	24-03-2015
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	31-10-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL50020.094.14