A comparative study of two types of wound closure after total hip replacement

Published: 07-12-2007
Last updated: 18-07-2024

Objective: Our goal is to prove that subcuticular sutured wounds will have less discharge than after closure with staples. Secondary outcome is patient satisfaction about wound and wound pain.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30892

Source
ToetsingOnline

Brief title
Wound closure after total hip arthroplasty

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Wound closure after totale hip replacement

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: staple, suture, total hip replacement (THR), wound closure

Outcome measures

Primary outcome

Main study parameters/endpoints: Wound discharge at day 4 post operative. 14 days after the operation the staples will be removed in the staple group and all wounds will be scored with the ASEPSIS wound score. And pain and comfort of the wound will be evaluated.

Secondary outcome

Patient satisfaction with treatment

Study description

Background summary

Rationale:
Development of a deep infection after total hip arthroplasty can have a disabling result for the patient. One of the predisposing factors for a deep infection is delayed wound healing and wound discharge. For skin closure after cemented total hip arthroplasty different methods can be used. Two common used methods are staples and subcuticular suture. Our hypothesis is that wounds closed with subcuticular sutures would have less discharge than stapled wounds.

Study objective

Objective: Our goal is to prove that subcuticular sutured wounds will have less discharge than after closure with staples. Secondary outcome is patient satisfaction about wound and wound pain.

Study design

Study design: Prospective randomised comparing study.

Intervention

Intervention: The skin will be closed subcuticular with Monocryl 3-0 (Ethicon) with Steri-strips (3M) or stapled with the PMW-35 stapler (Ethicon).

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation will not give additional risks for the patients because both methods are widely used well proved methods.

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

ostheoarthritis

Exclusion criteria

Diabetis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2007
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL18444.098.07