Minimal invasive knee surgery; is it less traumatic? A pilot study

Published: 06-07-2006
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To investigate of the minimal invasive approach is less traumatic in terms of inflammation and tissue damage?

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

Summary

ID

NL-OMON30180

Source
ToetsingOnline

Brief title
Minimal invasive knee surgery; is it less traumatic?

Condition

- Joint disorders

Synonym
artrosis, total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Maaslandziekenhuis
Source(s) of monetary or material Support: St Nuts-Ohra (lab bepalingen)

Intervention

Keyword: inflammation, MIS, tissue damage, TKA

Outcome measures

Primary outcome

Hemoglobin will be determined in terms of blood loss. Blood loss is also

measured during the operation and post-operatively in terms of drainporduction.

H-FABP tissue damage and IL-6 inflammation reactions

Furthermore the patient will be standard evaluated in terms of range of motion,

prothesis alignement and pain

Secondary outcome

None

Study description

Background summary

Replacement of the knee or hip is done in patients with reduced function because of the pain. The replacement leads to improvement of function and a better comeback in the community.
The last couple of years a lot of research has been done to reduce the hospitalisation and a less demanding surgery for the patient.
Recently is the minimal invasive approach (MIS) developed in which a prosthesis is placed with an incision <10cm.
When research is done to investigate of this procedure is less traumatic than this can lead to shorter hospitalisation, faster recovery and a better cosmetic appearance for the patient.

Study objective

To investigate of the minimal invasive approach is less traumatic in terms of inflammation and tissue damage?

Study design

The patients included in the study will be selected at random to one of the two study groups. One group is operated using the conventional approach and the

other with the minimal invasive approach.

Intervention

During the trial blood will be collected from the patients pre and postoperative (2, 4 and 6 hours and day 2 and 4 after surgery)

Study burden and risks

THe patients have the same risks and benefits than patients not included in the study. The only difference is the blood collection of the patients included in the study.

Contacts

Public
Maaslandziekenhuis

Walramstraat 23
6131 BK Sittard
Nederland
Scientific
Maaslandziekenhuis

Walramstraat 23
6131 BK Sittard
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- patients receiving a primary total knee arthroplasty
- patients with osteoarthritis or avascular necrosis

Exclusion criteria

- pregnancy
- clinical relevant disorders, like rheumatoid arthritis, previous knee surgery, standard use of anticoagulantia
- unwilling and unable to cooperate in the study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2006
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2006
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL11693.096.06