PAKA-trial Portal Anaesthesia after Knee Arthroscopy

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The study-objective of this prospective randomised dubbelblind clinical trial is to demonstrate superior anaesthesia with infiltration of the portals with 20cc of bupivacaine compared tot not giving portal anaesthesia.

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

Summary

ID

NL-OMON36706

Source
ToetsingOnline

Brief title
PAKA-trial

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
pain / dyscomfort

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anaesthesia, arthroscopy, knee, portal

Outcome measures

Primary outcome

pain score at 3 hours post-operative

Secondary outcome

pain score 1, 6, 24 hours post-operative.

satisfaction 24 hours postoperative

adjuvant consuption and time to first dose of adjuvant analgesics.

Study description

Background summary

Knee-arthroscopy is performed in day-care surgery. good post-operative analgesia is therefore important. for optimal analgesia oral and sometimes direct post-operative intravenous meidcation is used. To raise patientcomfort and decrease consumption of these adjuvant analgesics, adjuvant local portal anaesthesia could be beneficial.

Study objective

The study-objective of this prospective randomised dubbelblind clinical trial is to demonstrate superior anaesthesia with infiltration of the portals with 20cc of bupivacaine compared tot not giving portal anaesthesia.

Study design

Prospective randomised controlled double blind trial

Intervention

portal anaesthesia with 10 cc of bupivacaine 0.5% per portal.

Study burden and risks

for most patients ther is no more risk compared to not participating in the study because some surgeons already use portal anaesthesia.
For patients of doctors not using portal anaesthesia, the risk is an allergic reaction to bupivavaine. to our knowledge these reactions are seldom which should mean between 1:1000 and 1:10.000.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
undergoing arthroscopy of the knee under general anaesthesia.
age 18-75 years.
ASA Classification I or II.

signed informed consent

Exclusion criteria

Arthoscopig ligament reconstructions.
concurrent participation in other trials.
physical or mental handicaps limiting revalidation or understanding of the trial.
known intolerance for Bupivacaine

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2012
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bupivacaine
Generic name:	Bupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2011-003410-16-NL
CCMO	NL35270.018.11