Local infiltration analgesia with or without adrenaline in TKA

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25265

Source
Nationaal Trial Register

Brief title
LIA, TKA, UKA, adrenaline

Health condition

All patients who will undergo TKA placement are potential subjects for this pilot study

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

• VAS pain score direct post operative and 16:00H and 22:00H on the operative day.

• VAS pain score before and after the first mobilisation.

• VAS pain score at 8:00H, 16:00H and 22:00H till day of discharge

Secondary outcome

• Amount of post operative analgesia use direct post operative till day of discharge

• Time to first mobilisation

• Length of hospital stay

• Adverse events/complications: Intra-operative, post-operative during pilot study

Study description

Background summary

The aims of this pilot study are: to investigate whether LIA with ropivacaine is at least as effective in short term outcome as the widely used current method, LIA procedure with mixture of ropivacaine and adrenaline

Study objective

•LIA with ropivacaine will result in comparable clinical results in terms of post operative pain as LIA procedure with mixture of ropivacaine and adrenaline

•LIA with ropivacaine will result in comparable reduction of post operative analgesia use as LIA procedure with mixture of ropivacaine and adrenaline

•LIA with ropivacaine will result comparable early mobilisation and hospital discharge as LIA procedure with mixture of ropivacaine and adrenaline

•LIA with ropivacaine will result in comparable complications/adverse events as LIA procedure with mixture of ropivacaine and adrenaline

Study design

Pre, peri, post operative till discharge, 3 months and 1 year post operative

Intervention

Post operative LIA after TKA either with ropivacaine or the standard LIA procedure with ropivacaine and adrenaline mixture.

Contacts

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Eligibility criteria

Inclusion criteria

•Painful and disabled knee joint resulting from osteoarthritis

•High need to obtain pain relief and improve function

•Able and willing to follow instructions

•Consent form read, understood and signed by patient.

Exclusion criteria

•Active infection in knee

•General infection

•Distant foci of infections which may spread to the implant site

•Failure of previous joint replacement

•Pregnancy

•Contraindication for ropivacaine

•Contraindication for adrenaline

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-05-2014
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-09-2014
Application type:	First submission

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
NTR-new	NL4618
NTR-old	NTR4769
Other	3.035 : 13-T-112

Study results

Summary results
No advantage of adrenaline in the local infiltration analgesia mixture during total knee arthroplasty.
Schotanus MG, Bemelmans YF, van der Kuy PH, Jansen J, Kort NP.
Knee Surg Sports Traumatol Arthrosc. 2015 Jul 26. [Epub ahead of print]
PMID: 262109