Local analgesia in total knee replacement: The effect of local analgesia shots on ropivacaine levels in shed blood collected with a retransfusion device and in patients plasma.

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To quantify the amount of local anaesthetic in shed blood in the Bellovac ABT system and in the blood circulation of the patient. The primary objective is to detect the course of ropivacaine levels in the shed blood collected with the Bellovac ABT...

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

Summary

ID

NL-OMON34159

Source
ToetsingOnline

Brief title
LABELLO II; Single shots and ropivacaine levels

Condition

- Joint disorders

Synonym
joint wear (osteoarthritis), own blood donation (autologous blood transfusion)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: autologous reinfusion, local analgesia, ropivacaine, total knee replacement

Outcome measures

Primary outcome

Ropivacaine will be quantified in patient serum (0, 1, 3, 6, 7 and 18-24 h

after surgery) and in the shed blood collected with the Bellovac ABT system at

the same time points postoperative.

Secondary outcome

- VAS pain scores measured per protocol

- Opioid consumption (amount of morfine used with PCA pump) 24, 48 and 72hrs

- Several important time points will be documented; start operation, injection

of single shot, tourniquet release, leaving recovery and blood samples

Study description

Background summary

Evidence suggests that local analgesia after total knee replacement (TKR) provides better knee function in the postoperative period with less post-operative complications like nausea and vomiting as compared to conventional ways of pain treatment (i.e.opioids). The Bellovac ABT system; a technique to collect, filter and reinfuse shed blood, is also often used in TKR. Bellovac ABT is used as an alternative to allogeneic blood transfusion. A combination of both techniques however, is not common yet. Before routinely combining local analgesia with the Bellovac ABT technique we have to know the amount of ropivacaine in the shed blood collected with the Bellovac ABT system. As complement on the already collected data from earlier research is the course

of the ropivacaine levels in the collected shed blood.

Study objective

To quantify the amount of local anaesthetic in shed blood in the Bellovac ABT system and in the blood circulation of the patient. The primary objective is to detect the course of ropivacaine levels in the shed blood collected with the Bellovac ABT system and in patients plasma.

Study design

Patients will be asked to participate in the trial. After inclusion, patients will be operated and during surgery a field block is given using two single shots with ropivacaine and adrenaline. After closure of the subcutis and before the cutis will be closed a last block will be injected subcutaneous without adrenaline. After surgery, patients receive a Bellovac ABT (wound) drain in the knee joint. The blood collected with the Bellovac ABT system and blood samples from the patient will be collected at 0, 1, 3, 6, 7 and 18-24 (first postoperative morning) hours after operation when the wound drain will be removed.

Study burden and risks

Extra blood samples will be collected to quantify the ropivacaine in patient serum. Collection of shed blood in the Bellovac ABT does not imply extra risks of burden to the patient.

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

- primary TKP
- Haemoglobin level above 7.5 mmol/L
- both arms can be used for blood collection

Exclusion criteria

- allergic for used medication or other local anaesthetics
- major operation within 12 weeks before TKP surgery
- high risk patients for insultus epilepticus
- dutch language not mastered

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2011
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	NL33364.098.10