Local anaesthesia and Bellovac ABT.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22267

Source
NTR

Brief title
LABELLO study

Health condition

total knee arthroplasty, retransfusion, local anesthesia

Sponsors and support

Primary sponsor: Medical Center Haaglanden, the Hague

Intervention

Outcome measures

Primary outcome

Ropivacaine will be quantified in patient serum (0, 3, 6 and 24 h after surgery) and in the blood-tissue fluid collected and filtered in the Bellovac ABT system in order to be able to calculate systemic exposure after reinfusion of the blood.

Secondary outcome

VAS painscores.

Study description

Background summary

Evidence suggests that local anaesthesia 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). Good clinical results have been obtained with and without the use of indwelling catheters. The Bellovac ABT system; a technique to collect, filter and reinfuse blood and tissue fluid, 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 anaesthesia with the Bellovac technique we want to quantify the amount of local anaesthetic (if any) in the collected and retranfusable blood and tissue fluid. On the basis of these data the safety of combining local anaesthesia with the retransfusion of blood and tissue fluid will be assessed.

Study objective

To quantify the amount of local anaesthetic in blood and tissue fluid in the Bellovac ABT system and in the blood circulation of the patient. The primary objective is to quantify the cumulative ropivacaine level when the blood should be retransfused to the patient. As a secondary objective the quality of postoperative anaesthesia will be evaluated.

Study design

During hospitalisation.

Intervention

Administration of local anaesthetic (single shot and continuous infusion) in TKR. Blood and tissue fluid will be collected in a Bellovac ABT system and by venous sampling and used for quantification of local anaesthetics.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients must have pre-operative haemoglobin levels above 7.5 mmol/L;

2. Patients will be operated under spinal anaesthesia;

3. Male and non-pregnant female patients between 18-90 years of age;

4. Patients with BMI <40;

5. Patients are able to have a venous cannula in both arms;

6. Patients have normal renal function for their age (MDRD);

7. ASA classification score I-II.

Exclusion criteria

1. Patients with a major surgical procedure during the 12 weeks before the study-related operation;

2. Patients with documented allergy for the medication (ropivacaine, bupivacaine, NSAIDs, aminoacetophen or opiates) used in the study or any other local anaesthetic of the amino amide type;

3. Recent Myocardial Infarction or CVA (<3 months);

4. Patients with elevated risk of epileptic seizures;

5. Dutch language not mastered.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	28-04-2009
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	NL1683
NTR-old	NTR1784
Other	METC Medical Center Haaglanden : 08-132
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A