Local anaesthesia and Bellovac ABT.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22267

Bron
Nationaal Trial Register

Verkorte titel
LABELLO study

Aandoening

total knee arthroplasty, retransfusion, local anesthesia

Ondersteuning

Primaire sponsor: Medical Center Haaglanden, the Hague

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

During hospitalisation.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Haaglanden Medical Center
PO Box 432

B.J.W. Thomassen
Den Haag 2501 CK

The Netherlands
+31 (0)70 3303109

Wetenschappelijk

Haaglanden Medical Center
PO Box 432

B.J.W. Thomassen
Den Haag 2501 CK
The Netherlands
+31 (0)70 3303109

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2009
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-04-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1683
NTR-old	NTR1784
Ander register	METC Medical Center Haaglanden : 08-132
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A