Effect of Pregabaline and S-Ketamine on knee function after total knee arthroplasty.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28359

Source
NTR

Brief title
THE EFFECT OF PREGABALIN AND S-KETAMINE ON THE KNEE FUNCTION OUTCOME, AFTER TOTAL KNEE ARTHROPLASTY

Health condition

PREGABALIN
S-KETAMINE
LOCAL KNEE INFILTRATION
TKA

Sponsors and support

Primary sponsor: no sponsor,
performer is UMCN
Source(s) of monetary or material Support: no extra funding source / UMCN is the performer

Intervention

Outcome measures

Primary outcome

1. Range of motion / Knee flexion angle: The knee flexion angle is measured from the first postoperative day (Day 1), until the day of discharge (DD), by a physical therapist (flexion_1,flexion _2, flexion_3, flexion_4, flexion_5, flexion_DD);

2. Pain: The standard Numeric Rating Scale (NRS) is used to measure pain. The patient can grade the intensity of knee related pain on a scale of 0-10, where 0 means no pain and 10 is the worst imaginable pain. The NRS is recorded on the day 0 in the recovery: NRS0-R, and in the ward: NRS0-W; on the day 1 (NRS1 four times a day); on the day 2 (NRS2 four times a day) by a nurse on the ward. From day one to day five, a physical therapist will note the dynamic pain scores (NRS-d), during the exercises (NRS1-d to NRS5-d);

3. Piritramide consumption: All patients are instructed to use PCA-piritramide, if they have knee pain. They may receive a 1 mg piritramide on demand, during the first 48 hours. Piritramide is given as a rescue medication and the total consumption per day will be noted;

4. S-Ketamine / pregabalin possible side effects;

5. The state of sedation will be assessed as a 4-point score:
0 = no sedation, 1 = mild sedation, 2 = moderate sedation, 3 = severe sedation during the first 24 hours;

6. Postoperative nausea and vomiting: PONV will be registered as: absent, mild or heavy;

7. Length of hospital stay: The length of hospital stay is noted as the number of days between the day of surgery and discharge from the hospital (or readiness to discharge);

8. Patients` satisfaction: The patient’s satisfaction with the postoperative analgesia is recorded before discharge. This is done on a 4 point scale; 1 = poor, 2 = fair, 3 = good, or 4 = excellent.

Secondary outcome

An independent physician measures the knee function six weeks, three months and one year after surgery. In addition, pain at rest and movement wil be scored, and the satisfaction with the TKA assessed, each time.
The Knee Society score (KSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaires are used. The KSS is divided in a part with knee related questions (KSS_knee) and a functional scale (KSS_function). The WOMAC is divided in a pain scale (WOMAC_pain), stiffness scale (WOMAC_stiffness) and a functional scale (WOMAC_function). All subscales of the KSS and WOMAC have a range of 0-100.

Study description

Background summary

Background:

TKA often produces severe postoperative pain. Reduction of pain is an important factor in the early rehabilitation of these patients. There is some evidence, that the addition of pregabalin and s-ketamine may not only reduce the acute postoperative pain, but also the incidence of chronic postoperative pain in these patients. Some studies also show that the intra-articular injection of corticosteroids may be beneficial and even shorten the hospital stay. Lately, there are randomized, controlled studies showing that intra and peri-articular infiltration with local anesthetics, after TKA, due to its simplicity and low complication risk, may be a good alternative to different loco-regional techniques such as femoral block and epidural analgesia.

Methods:

This study is a prospective, randomized, double blind, controlled evaluation of two methods of analgesia after TKA. The patients will be operated under spinal anesthesia. The intra- and peri-articular local anaesthetic infiltration with ropivacaine/adrenaline/kenacort®, will be given (during the operation) to the study group, with the addition of pregabalin and s-ketamine in the first postoperative days. In the control group, the same local anesthetic knee infiltration will be performed during the surgery. Only, instead of pregabalin per os, the control group is getting placebo and instead of s-ketamine normal saline infusion.
For the process of randomization computer generated random numbers will be used. Our research question is:
Can the addition of s-ketamine and pregabalin reduce the acute pain and enhance the range of motion in the early postoperative period after TKA? The secondary goal is to determine if the edition of s-ketamine and pregabalin can reduce the incidence of chronic pain after TKA and improve the long term functional results?

Study objective

The goal of this study is to determine whether we can achieve any functional benefits by addition of pregabaline and s-ketamine to local intra-articular analgesia (LIA).

Our primary research question is: Can the addition of s-ketamine and pregabaline to LIA reduce the acute pain and enhance the range of motion in the early postoperative period after TKA?

The secondary goal is to determine if the edition of s-ketamine and pregabaline to LIA can reduce the incidence of chronic pain after TKA and improve the long term functional results.

Study design

1. Day of surgery;

2. The first five postoperative days;

3. Day of discharge;

4. 6 weeks after TKA;

5. 3 months after TKA;

6. 1 year after TKA.

Intervention

In the study group, 150 mg of pregabalin will be given per os with premedication. It will be continued, twice a day during the first three postoperative days. The dose will be reduced to 75 mg two times a day in elderly patients. The control group will get placebo.

At the beginning of the surgery, the study group will also receive an intravenous bolus of 5-10 mg S-ketamine. This will be followed by a 24 hours continuous infusion, at the rate of 5-10 mg/hour (dose reduction for elderly).The control group will get normal saline infusion instead.

Contacts

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Eligibility criteria

Inclusion criteria

Patients aged 18 to 80 years, listed for total knee arthroplasty are eligible for this study.

Exclusion criteria

1. Patient refusal;

2. Preexisting neurological or psychiatric illnesses;

3. Chronic pain syndrome;

4. Alcohol or drug abuse;

5. Difficulties in communication or expected inability to understand patient-controlled analgesia;

6. Rheumatoid arthritis;

7. Revision knee surgery;

8. Participation in another study.

Study design

Design

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

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2633
NTR-old	NTR2761
Other	ABR : 35558
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A