DOES THE ADDITION OF PREGABALIN AND S-KETAMINE TO LOCAL KNEE INFILTRATION, IMPROVE THE POSTOPERATIVE KNEE FUNCTION OUTCOME AFTER TOTAL KNEE ARTHROPLASTY?

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The primary goal of this study is to determine if there are any benefits in addition of pregabalin and s-ketamine to local knee infiltration with ropivacaine/adrenaline/kenacort®, regarding the analgesia and the early mobilization in the study group...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36143

Source
ToetsingOnline

Brief title
THE EFFECT OF PREGABALIN AND S-KETAMINE AFTER TOTAL KNEE ARTHROPLASTY

Condition

- Bone and joint therapeutic procedures

Synonym
posoperative analgesia after total knee arthroplasty

Research involving

Human

Sponsors and support

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

Intervention

Keyword: LOCAL KNEE INFILTRATION, PREGABALIN, S-KETAMINE, TKA

Outcome measures

Primary outcome

PRIMARY PARAMETER IS:

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 as (flexion_1,flexion _2, flexion_3, flexion_4, flexion_5, flexion_DD).

Secondary outcome

SECONDARY PARAMETERS ARE:

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 a day one to day five, a physical therapist will note the dynamic pain scores (NRS-d), during the exercises (NRS1-d to NRS5-d).

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.

S-Ketamine / pregabalin possible side effects

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.

Postoperative nausea and vomiting

PONV will be registered as: absent, mild or heavy.

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).

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.

An independent physician will measure the knee function six weeks, three

months and one year after surgergery. In addition, pain at rest and movement will 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

ABSTRACT

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. For the process of randomization computer generated random numbers will be used.
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 will get placebo and instead of s-ketamine, the normal saline infusion.The studie medication will be prepared by the Department of Clinical Pharmacology and will be blinded for the patient and the resarch team.
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 primary goal of this study is to determine if there are any benefits in addition of pregabalin and s-ketamine to local knee infiltration with ropivacaine/adrenaline/kenacort®, regarding the analgesia and the early mobilization in the study group, compared to the control group (getting placebo).
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 design

This study is a prospective, randomized, double blind, controlled evaluation of the value of the additional analgesics after TKA. The surgery will be done under spinal anesthesia.During surgery, intra- and peri-articular local anaesthetic infiltration with ropivacaine/adrenalin/kenacort®, will be given to the study group, with the addition of pregabalin and s-ketamine in the first postoperative days. In the control group, the same knee infiltration will be performed, only instead of pregabalin per os, the control group will get placebo, and instead of s-ketamine, the normal saline infusion.
The studie medication will be prepared by the Department of Clinical Pharmacology and will be blinded for the patient and the resarch team.
For the process of randomization computer generated random numbers will be used. The head orthopedic nurse will open the envelope before the operation (deciding to which group the patient belongs) and bring the study medication to the operation theatre. This person will be responsible for the correct process of randomization and registration of the given medication.
Based on power analysis, 60 patients scheduled for primary TKA at the Radboud University Nijmegen Medical Centre, The Netherlands, will be randomly allocated to either study or control group, during the period of two years.

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 ABOVE THE AGE OF 65 AND ASA III. The control group will get placebo.

At the beginning of a surgery, 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 2,5-10 mg/hour (dose reduction for ASA III AND ABOVE THE AGE OF 65 YEARS.).The control group will get normal saline infusion, instead.

Study burden and risks

There is no extra burden for these patients. Only the registration of the data of the knee related pain and the achieved range of motin will be more frequently recorded. All adverse events or complications will be registered. The research will not cause any delay or change in the operative procedure. The additional antihyperalgesic medication (pregabalin and s-ketamine) may cause drowsiness or dissiness. The patient will receive both of these drugs on the day of operation, will be closely observed and will stay in bed.
At the beginning of the 1st postoprative day s-ketamine will be stopped (7 am). Pregabalin will be continued per os during the first three postoperative days (during the hospitalization, only).
The dose of both drugs will be adjusted according to physical status and the age of the individual patient.The dose will be reduced in elderly and sick patients.
Expected benefits are: improvement of early and long terme functional results after TKA.

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

patients scheduled for total knee arthroplasty

Exclusion criteria

patient refusal; preexisting neurological or psychiatric illnesses; chronic pain syndrome; alcohol or drug abuse; SUSPECTED POSSIBILITY OF POSTOPERATIVE DELIRIUM , difficulties in communication or expected inability to understand patient-controlled analgesia; rheumatoid arthritis, revision knee surgery or participation in another study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2011
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	pregabalin
Registration:	Yes - NL intended use
Product type:	Medicine
Generic name:	s-ketamine 5 mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2011-002019-27-NL
CCMO	NL35558.091.11
Other	NRT 9102