

Ketamine to reduce postoperative pain in back surgery

Submission date 03/10/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Spinal fusion surgery involves joining together bones in the spine so there is no movement between them. Common analgesics (painkillers) such as paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs) are rarely effective on their own after spinal fusion surgery. Opioids are the most effective analgesics but they have many side effects, such as vomiting and constipation. Ketamine is an old anaesthetic drug that also has analgesic properties. Ketamine reduces the need for opioids after the operation and therefore helps to reduce the side effects caused by opioids. However, the ideal dose of ketamine is not known. The aim of this study is to determine the best dose of ketamine to use to reduce the need for opioids while avoiding side effects.

Who can participate?

Patients aged over 18 undergoing elective posterior lumbar fusion surgery

What does the study involve?

Participants are randomly allocated into three groups. The first group are given placebo (a dummy drug) during the operation. The second and third groups are given different doses of ketamine during the operation. After the operation the participants' need for opioid medication is recorded.

What are the possible benefits and risks of participating?

Participants treated with ketamine may benefit from improved pain relief (analgesia) after spinal fusion surgery along with fewer side effects caused by opioid medication. Possible risks are side effects caused by ketamine. The most common side effect of ketamine is altered mental state. However, that can be prevented using the drug diazepam.

Where is the study run from?

Helsinki University Central Hospital Töölö Hospital and Pain Clinic (Finland)

When is the study starting and how long is it expected to run for?

January 2013 to December 2014

Who is funding the study?
Helsinki University Central Hospital (Finland)

Who is the main contact?
Dr Elina Jokinen

Contact information

Type(s)
Scientific

Contact name
Dr Elina Jokinen

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Additional identifiers

Protocol serial number
KETTO201200074726

Study information

Scientific Title
Administration of S-Ketamine during spinal surgery to reduce postoperative pain

Acronym
KETTO

Study objectives
It is known that administration of ketamine during surgery reduces the need of opioid medication in the postoperative period. However, the ideal dose of ketamine is not known.

Hypothesis: The more ketamine is being administered during surgery, the greater is the opioid-sparing effect in the postoperative period. However, it is assumed that the number of side effects is also greater.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Valtakunnallinen lääketieteellinen tutkimuseettinen toimikunta TUKIJA, 12/03/2012, ref: 36/06.00.01/2012

Study design

Prospective randomized double-blinded placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Optimal dose of S-ketamine to reduce the need of opioid medication in the postoperative period

Interventions

The study will involve 192 adult patients undergoing elective posterior lumbar fusion surgery. The patients will be randomized into three groups: 64 patients will be given placebo (NaCl 0,9%), 64 patients will be given an infusion of S-ketamine 2ug/kg/min and 64 patients will be given an infusion of S-ketamine 10ug/kg/min during the surgery. The consumption of oxycodone with PCA-device is being registered 48-hours after the surgery.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Evaluate the effect of different dosages of S-ketamine in the intraoperative period on the need of postoperative opioid medication

Key secondary outcome(s)

Evaluate the postoperative confusion, pain and depression in the different study groups

Completion date

31/12/2014

Eligibility**Key inclusion criteria**

Adult patients (18 years and older) undergoing elective posterior lumbar fusion surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

198

Key exclusion criteria

1. BMI>35
2. Unstable ischaemic cardiac disease
3. Increased intracranial pressure
4. Increased intraocular pressure
5. Gravidity
6. Lactation
7. Hypersensitivity or allergy to ketamine, oxycodone, propofol or remifentanyl
8. Severe psychiatric disease
9. Unwillingness or inability to use PCA-device
10. Inability to use NRS-pain scale

Date of first enrolment

01/01/2013

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

Finland

Study participating centre

Helsinki University Central Hospital

Helsinki

Finland

00251

Sponsor information

Organisation

Helsinki University Central Hospital (Finland)

ROR

<https://ror.org/02e8hzh44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsingin ja Uudenmaan Sairaanhoitopiiri

Alternative Name(s)

Helsinki University Central Hospital, HUS

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	22/01/2021	Yes	No
Basic results		27/02/2019		No	No