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Ketamine to reduce postoperative pain in back surgery

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
10/10/2012

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Primary study design
Interventional

Study design
Prospective randomized double-blinded placebo-controlled trial

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 patienst 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. Hypersensivity or allergy to ketamine, oxycodone, propofol or remifentanil
8. Severe psychiatric disease
9. Unwillingness or unability to ude 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/02e8hzf44

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