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Does S(+)-ketamine or the combination of S(+)-ketamine and magnesium reduce post-operative opioid requirements after abdominal surgery?

Submission date
15/10/2010

Registration date
28/04/2011

Last Edited
28/04/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Does S(+)-ketamine or the combination of S(+)-ketamine and magnesium reduce post-operative opioid requirements after abdominal surgery? A prospective double blinded randomised controlled trial

Study objectives
The aim of this study was to investigate if the addition of S(+)-ketamine and the addition of the combination of S(+)-ketamine with magnesium sulphate would result in a reduction of opioid requirements compared to a placebo in an existing regimen of post-operative pain treatment with patient controlled analgesia (PCA) with an opioid (piritramide). Secondary aim was the assessment of the effects on post-operative pain scores (Visual Analogue Scale [VAS]) and the incidence of side-effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee Maastricht University Medical Center (MUMC+) approved on the 8th March 2002 (ref: MEC.A.99-107/1)

Study design
Prospective double blinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elective open abdominal surgery

Interventions
Anaesthesia was given in a standardised way; premedication was given using midazolam 3.75 mg orally. Induction using propofol 2 mg/kg, rocuronium 0.6 mg/kg and remifentanyl 0.1 - 1 µg/kg /min by continuous infusion. For maintenance of anaesthesia sevoflurane and remifentanil 0.1 - 1 mg/kg/min were used. No loco-regional blocks were applied.

Study medication was given intravenously (i.v.) as a bolus during induction of the anaesthesia followed by a continuous fixed infusion rate calculated for body weight during 24 hours.

In group C (the control group), patients received a placebo consisting of sodiumchloride (NaCL) 0.9%.

In group K the study medication consisted S(+)-ketamine. A bolus was given of 0.2 mg/kg followed by an infusion at a rate of 2 µg/kg/min.

In group KM the study medication consisted of S(+)-ketamine and magnesium sulphate (MgSO4). A bolus was given of S(+)-ketamine 0.2 mg/kg and MgSO4 of 15 mg/kg followed by an infusion at a rate of 2 µg/kg/min S(+)-ketamine and 5 mg/kg/h MgSO4.

Before the emergence of the anaesthesia every patient received an loading dose piritramide 0.15 mg/kg i.v.. At the PACU all the patients received a patient-controlled-analgesia device (PCA) consisting piritramide without background infusion and a bolus set at 1 mg with a lockout time of 5 minutes.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
S(+)-ketamine, magnesium

Primary outcome(s)
Total amount of piritramide used at 48 hours

Key secondary outcome(s))
1. Piritramide use at 12 and 24 hours
2. VAS pain scores at 0.5, 1, 2, 3, 4, 8, 12, 24 and 48 hours
3. Vital parameters
4. Incidence of side-effects

Completion date
09/05/2007

Eligibility

Key inclusion criteria
1. Patients with category I and II American Society of Anesthesiologists (ASA) classification
2. Aged between 18 to 70 years old, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Extensive previous use of pain therapy
2. Previous strong side-effects caused by ketamine

3. Alcohol abuse
4. Use of psychotropics
5. Severe mental disease
6. Reintervention laparotomy due to complications

Date of first enrolment
15/03/2004

Date of final enrolment
09/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Postbus 5800
Maastricht
Netherlands
6202AZ

Sponsor information

Organisation
Maastricht University Medical Centre (Netherlands)

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht University Medical Centre (Netherlands) - Department of Anesthesiology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration