

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

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Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/04/2011	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Total amount of piritramide used at 48 hours

Secondary outcome measures

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

Overall study start date

15/03/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.azm.nl>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration