Finding best practice: use of s-ketamine peropertively and in patient controlled analgesia in the treatment of pain after major abdominal surgery

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1.To compare the morphine sparing effect of low-dose ketamine in peroperative infusion and in post operative PCA (Morphine use)2.To compare the occurence of side effects.3.To compare the analgesic potential of the two therapies (VAS Scores)4.To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic and nontherapeutic effects (excl toxicity)
Study type	Observational invasive

Summary

ID

NL-OMON32227

Source
ToetsingOnline

Brief title
Use of s-ketamine peroperatively and in patient controlled analgesia

Condition

- Therapeutic and nontherapeutic effects (excl toxicity)
- Therapeutic procedures and supportive care NEC

Synonym
Analgesia in abdominal surgery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abdominal surgery, analgesia, Ketamine

Outcome measures

Primary outcome

1. The total morphine use over 72 hours.

2. The occurence of side effects.

3. The VAS scores per study group.

Secondary outcome

1. Evaluation of the levels of the amino-acids (glutamate, glycine, tryptofane,

arginine e.g) and the effect of analgesia on them.

Study description

Background summary

The administration of morfine for postoperative analgesia after major surgery using IV patient-controlled analgetics is a common practice. However it may be associated with important side-effects such as respiratory depression, nausea and mvomiting, sedation, hallucinations, urinary retention and prolonged ileus. The most important side effects are mediated by agonism of the mu-receptor.
A second receptor modulating pain perception present in the central nervous system is the N-methyl D-aspartate (NMDA) receptor. When NMDA receptors are stimulated by afferent nociceptive input, they activate a neuronal sensitization process that enhances pain perception.
Ketamine, an NMDA receptor antagonist, is known to induse dissociate anesthesia. The combination of morfine and ketamine has been shown to induce an increase in analgesic effect while a tendency towards a lower incidence of side effects was observed.

Study objective

1.To compare the morphine sparing effect of low-dose ketamine in peroperative infusion and in post operative PCA (Morphine use)
2.To compare the occurence of side effects.
3.To compare the analgesic potential of the two therapies (VAS Scores)
4.To evaluate the effect of the therapies on the levels of amino-acids

Study design

A double blind randomized control trial with 2 groups:
Both groups shall receive a standardized post operatieve analgesic treatment with a Morphine PCA pump.
1. Peroperative bolus administration of saline, post operative 50ml i.v. of saline over 48 hrs.
2. Peroperative bolus administration of S-Ketamine, post operative 2 microgram/kg/min i.v. of S-Ketamine over 48 hrs.

Study burden and risks

nvt

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

The patient has provided written informed consent prior to admission to the study
The patient is between 18 and 70 years of age

Exclusion criteria

The patient has a history of uncontrolled chronic disease which would contra-indicate study participation.
The patient has severe systemic disease that limits activity and is a constant threat to life (ASA IV).
The patient has a history of chronic substance abuse within the last 3 months.
The patient has a history of psychiatric disorders.
The patient has a history of hypersensitivity to one of the study drugs.
The patient has a history of severe chronic respiratory disorders.
The patient is either breastfeeding or pregnant.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-10-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest
Generic name:	(S)-Ketamine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Morfine
Generic name:	Morfine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-09-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2008-001700-23-NL
CCMO	NL22455.078.08