S-ketamine for acute and chronic headache after brainsurgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24994

Source
Nationaal Trial Register

Brief title
ESPAIN

Health condition

Post operative craniotomy pain.

postoperative pain
post-craniotomy headache
drug resistant epilepsy
temporal lobectomy

post-operatieve hoofdpijn
craniotomie pijn
resistente epilepsie
temporale lobectomie

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum
Department of Neurosurgery and Anesthesiology
Source(s) of monetary or material Support: Maastricht Universitair Medisch Centrum
Department of Neurosurgery and Anesthesiology

Intervention

Outcome measures

Primary outcome

Primary endpoint is the total postoperative opioid consumption at the 7th postoperative day with interim measurements at 24, 48, 72 and 96 hours.

Secondary outcome

Secondary endpoints are the postoperative pain scores (VAS+NRS), patient health-related quality of life, psychological parameters, length of hospital stay and adverse events.

Study description

Background summary

Effective treatment of postoperative pain after craniotomy, especially temporal lobectomy for drug resistant epilepsy, is a challenge. With the current treatment of acetaminophen and opioids, patients still have moderate to severe pain complaints, whereby increasing the amount of opioids seems to have little effect. S-ketamine could be an alternative as add-on medication to opioids. It has been shown to be effective and safe in low-doses, whereby it reduces both the total opioid consumption and the postoperative pain scores. Until now, the addition of s-ketamine to opioids as part of a multimodal approach for postcraniotomy pain has never been studied.

The objective of this study is to investigate the effectiveness of s-ketamine as add-on medication to a multimodal pain approach with acetaminophen and opioids, compared to placebo.

The study design is a prospective, randomized, double blind, placebo-controlled, two-arms clinical trial. Patients are randomized by computer to either be part of the intervention group and receive a 0.25mg/kg bolus s-ketamine followed by a continuous infusion of 0.1mg/kg/u s-ketamine for 48 hours as add-on medication to acetaminophen and opioids, or be part of the control group and receive a placebo infusion (NaCl 0.9%) in similar administration and dose as the intervention. The study medication will start prior to the skin incision.

The study population consists of adult patients (18-65 years) with drug resistant temporal lobe epilepsy who are scheduled for a temporal lobectomy under general anesthesia.

The primary study outcomes is the total postoperative opioid consumption at the 7th postoperative day with interim measurements at 24, 48, 72 and 96 hours. Secondary study outcomes are the postoperative pain scores (VAS+NRS), patient health-related quality of life, psychological parameters, length of hospital stay and adverse events.

Anaesthesiologists use s-ketamine as part of their multimodal pain approach in daily practice. Low-dose s-ketamine is safe to administer and is not associated with serious side effects or a significant increase of adverse events.

Prior to the operation, all patients will receive questionnaires about health-related quality of life (RAND-36-item Health Survey [RAND SF-36]), surgical fear (Surgical Fear Questionnaire [SFQ]), depression (Center for Epidemiologic Studies Depression scale [CES-D]), pain catastrophizing (Pain Catastrophizing Scale [PCS]), severity of the patient's pain (Brief Pain Inventory-Short Form [BPI-SF]), neuropathic pain (Douleur Neuropathique 4 Questions [DN4]) and a questionnaire inquiring the characteristics of the headache. Postoperatively, as described above, data are collected (VAS+NRS scores, total amount of analgetics, adverse events). Furthermore, patients will be asked to fill in a pain (headache) diary at postoperative day 1-4 and at day 7 and the occurrence of delirium will be tested in the 7 postoperative days with the Delirium Observation Screening (DOS) scale. At day 7, a final pain (headache) assessment will be taken. A follow up questionnaire will be sent to each operated patient after 3 and 6 months to evaluate the course of chronic post-craniotomy pain (headache).

Study objective

The addition of s-ketamine to a multimodal pain approach reduces the total postoperative opioid consumption and pain experience as estimated by the Visual Analogue Scale (VAS) and Numeric Rating Scale (NRS) scores.

Study design

Postoperative opioid consumption will be measured at 24, 48, 72 and 96 hours and at the 7th postoperative day.

After the operation, all patients will be transferred to the post anaesthesia care unit (PACU), where adverse events and pain scores are registered. Pain scores (VAS+NRS) will be measured at arrival at the PACU, after 1 and 2 hours postoperatively and just before the patient is leaving for the medium care. Additionally patients will fill out a patient diary with pain scores registered at day 1,2,3,4 and 7 postoperatively.

The patient health-related quality of life and psychological parameters will be measured in the baseline questionnaire prior to the operation and in the follow-up questionnaires completed after 3 and 6 months postoperatively.

Intervention

Patients are randomized by computer to receive either a 0.25mg/kg bolus s-ketamine followed by a continuous infusion of 0.1mg/kg/u s-ketamine or a placebo infusion (NaCl 0.9%) for 48 hours. The study medication will start prior to the skin incision.

Contacts

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Eligibility criteria

Inclusion criteria

- Age >18 years

- Elective resective surgery for drug-resistant temporal lobe epilepsy

- Drug-resistant epilepsy, based on: (1) chronic, focal epilepsy; (2) not seizure free with antiepileptic medication; (3) no medication options due to adverse effects

- Signed informed consent for trial participation

Exclusion criteria

- Declined informed consent

- Allergy to any of the trial medications

- Current chronic pain, such as, but not limiting to, migraine or other headaches.

- Chronic pain treatment with use of different kinds of pain medication.

- Alcohol, hard- or soft drug abuses

- Inability to complete questionnaires or language barrier

- History of psychiatric complaints for which treatment was performed

- History of craniotomy or subdural electrode implantation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-08-2018
Enrollment:	62
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-07-2017
Application type:	First submission

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
NTR-new	NL6305
NTR-old	NTR6480
Other	EudraCT : 2017-002616-13

Study results