

S-ketamine for acute and chronic headache after brainsurgery

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24994

Bron

Nationaal Trial Register

Verkorte titel

ESPAIN

Aandoening

Post operative craniotomy pain.

postoperative pain
post-craniotomy headache
drug resistant epilepsy
temporal lobectomy

post-operatieve hoofdpijn
craniotomie pijn
resistente epilepsie
temporale lobectomie

Ondersteuning

Primaire sponsor: Maastricht Universitair Medisch Centrum
Department of Neurosurgery and Anesthesiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 outcome 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).

Doel van het onderzoek

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.

Onderzoekopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	14-08-2018

Aantal proefpersonen: 62
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 04-07-2017
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6305
NTR-old	NTR6480
Ander register	EudraCT : 2017-002616-13

Resultaten