

Postoperative analgesia for supratentorial craniotomy

Submission date 17/04/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/04/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

People who have brain surgery (craniotomy) as part of their treatment are very likely to experience severe pain after the surgery. Controlling pain after surgery with pain killers is very important because it can keep the patient comfortable and may help them recover faster. The sooner people are up and about after an operation, the less likely they are to develop complications, such as blood clots or pneumonia. Unfortunately, there is no agreed way to treat pain in patients who have had craniotomy surgery. Morphine is a very strong pain killer which is most often used to relieve post-operative and severe pain. Morphine can be given to patients by using a patient-controlled analgesia (PCA) pump. The pump is computerised so that it safely permits the patient to push a button and receive small amounts of pain medicine into their intravenous (IV) drip. Morphine is not suitable for everyone and can react with a variety of other medications or medical conditions. The aim of this study is to test how well other pain killers work to help people manage pain after a craniotomy, alongside PCA morphine. This study will also see whether other pain killers can reduce the amount of morphine patients take after surgery, and look at the side effects people experience with morphine when they have taken other pain killers.

Who can participate?

Adults scheduled for supratentorial craniotomy surgery.

What does the study involve?

Participants are randomly allocated into one of four groups. Those in group 1 (intervention group) are given the pain killer dexketoprofen. Those in group 2 (intervention group) are given the pain killer paracetamol. Those in group 3 (intervention group) are given the pain killer metamizol. Those in group 4 (control group) are given a 'dummy' pain killer (saline). All participants have PCA pump morphine. Participants are assessed for pain for the first 24 hours after surgery.

What are the possible benefits and risks of participating?

The drugs used in this study are routinely used to treat postoperative pain. All potential side-effects are discussed with participants at the start of the trial.

Where is the study run from?
University of Istanbul (Turkey)

When is the study starting and how long is it expected to run for?
January 2013 to January 2015

Who is funding the study?
University of Istanbul (Turkey)

Who is the main contact?
Professor O Korkmaz Dilmen

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Postoperative analgesia for supratentorial craniotomy: a randomised controlled trial

Study objectives
The prevalence of moderate to severe pain is high in patients following craniotomy. Optimal analgesic therapy is very important as pain may cause severe problems. However, there is no consensus regarding analgesic regimen for post-craniotomy pain. The aim of this study is to investigate the effects of morphine and non-opioid analgesics on post-craniotomy pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Cerrahpasa School of Medicine, 10/07/2013, ref: 83045809/18230

Study design

Prospective randomised double blind placebo controlled interventional single centre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-supratentorial craniotomy pain

Interventions

Participants are allocated to one of four groups. All patients receive morphine-based patient controlled analgesia for 24 hours following surgery, in addition to one of the following:

1. Intravenous dexketoprofen (50mg)
2. Intravenous paracetamol (1g)
3. Intravenous metamizol (1g)
4. Intravenous saline (0.9%) (placebo)

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Dexketoprofen Paracetamol Metamizol Morphine

Primary outcome(s)

Pain intensity is assessed during the first 24 hours post-surgery using the visual analogue scale (VAS) (at the 10th minute, 1, 2, 6, 12, and 24 hours postoperatively).

Key secondary outcome(s)

Assessed during the first 24 hours post-surgery (at the 10th minute, 1, 2, 6, 12, and 24 hours postoperatively):

1. Morphine consumption
2. Morphine-related side effects
3. Ramsay Sedation Scale (RSS)
4. Blood pressure
5. Heart/respiratory rate

Completion date

01/01/2015

Eligibility

Key inclusion criteria

1. American Society of Anesthesiology (ASA) classification I-II or III
2. Aged 18 - 70
2. Scheduled for elective supratentorial craniotomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Neurological disorders hindering communication
2. Aphasia
3. Glasgow Coma Score (GCS) less than 15
4. Drug or alcohol addiction
5. Chronic pain
6. Raised intracranial pressure
7. Allergies to any of the drugs used in this study
8. Hepatic or renal dysfunction
9. Peptic ulcer disease
10. Dementia

Date of first enrolment

01/07/2013

Date of final enrolment

01/01/2015

Locations**Countries of recruitment**

Türkiye

Study participating centre

University of Istanbul

Cerrahpasa School of Medicine

Istanbul

Türkiye

34000

Sponsor information

Organisation

University of Istanbul

ROR

<https://ror.org/03a5qrr21>

Funder(s)**Funder type**

University/education

Funder Name

University of Istanbul (Turkey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other