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Postoperative analgesia for supratentorial craniotomy

Submission date
17/04/2015

Recruitment status
No longer recruiting

Registration date
27/04/2015

Overall study status
Completed

Last Edited
27/04/2015

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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).

Secondary outcome measures
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

Overall study start date
01/01/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
83

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
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34000

Sponsor information

Organisation
University of Istanbul

Sponsor details
Cerrahpasa School of Medicine
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03a5qrr21

Funder(s)

Funder type
University/education

Funder Name
University of Istanbul (Turkey)

Results and Publications

Publication and dissemination plan
Manuscript is due for submission to a journal.

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other