Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effects of maintaining remifentanil infusion until tracheal extubation on the recovery profile and hemodynamic variables in the patients with elective craniotomy

Protocol summary

Summary

In a prospective randomized doubble blind clinical trial, 62 patients with ASA class I-II, undergoing elective supratentorial craniotomy surgery under general anaesthesia using total intravenous anesthesia (propofol and remifentanil) will be allocated randomly into two 31 patients group, case and control group, during emergence from anaesthesia. At the end of surgery, propofol will stop and the infusion of remifentanil will be stopped in the control group but maintained in the remifentanil group with half maintenance dose until extubation. Heart rate (HR), mean arterial pressure (MAP), minogue scale and recovery profiles will be measured and copared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110711398N1**
Registration date: **2013-05-04, 1392/02/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Deputy of medicine faculty, Tehran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-04-09, 1392/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of maintaining remifentanil infusion until tracheal extubation on the recovery profile and hemodynamic variables in the patients with elective craniotomy

Public title

Maintaining of remifentanil infusion until extubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who candidated to supratentorial craniotomy, Age from 18 to 65 years, ASA physical class I-II, preoperative GCS > 13 Eexclusion criteria: age> 65 <18 years, physical class ASA > II, GCS< 13, any allergy to the drugs of study, history of smoking, COPD, chronic cough, asthma, HTN, difficult airway and recent upper respiratory tract infections

Age

From **18 years** old to **65 years** old

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University Of Medical Sciences Ethics Committee
Street address
Tehran University Of Medical Sciences, Ghods St. Keshavarz Blvd.
City
tehran
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Approval date
2013-02-16, 1391/11/28
Ethics committee reference number
91/D/130/2999

Health conditions studied

1

Description of health condition studied
Craniotomy of supratentorial lesion
ICD-10 code
D33
ICD-10 code description
Brain, supratentorial

2

Description of health condition studied
Craniotomy of supratentorial lesion
ICD-10 code
C71
ICD-10 code description
تومور بدخیم مغز

3

Description of health condition studied
Craniotomy of supratentorial lesion
ICD-10 code
D43.0
ICD-10 code description
Brain, supratentorial

Primary outcomes

1

Description
coughing & bucking intensity
Timepoint
during tracheal extubation
Method of measurement
Minogue Scale

2

Description
Mean Arterial Pressure
Timepoint
Each 2 minutes from last skin suture or Mayfield opening until extubation and each 2 minutes after extubation until 10 minute later/each 5 minutes until 15 minute later in recovery room
Method of measurement
Automatic noninvasive sphigmomanumeter

3

Description
Heart rate
Timepoint
Each 2 minutes from last skin suture or Mayfield opening until extubation and each 2 minutes after extubation until 10 minute later/each 5 minutes until 15 minute later in recovery room
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Time interval to awakening after discontinuing of anesthesia drug
Timepoint
Verbal stimulation every min after discontinuing of propofol
Method of measurement
Time to opening of eye with stimulation by cornometer

2

Description
Nausea & vomiting pervalance and intensity
Timepoint
Each 15 minutes until 1 hour in recovery room

Method of measurement
Four points score: 1 no sign, 2 mild, 3 moderate, 4 severe

3

Description
Concsiousness level
Timepoint
Each 15 minutes until 1 hour in recovery room
Method of measurement
GCS (Glasco coma scale)

4

Description
Reoperation incidance rate
Timepoint
Till 48 houres after operation
Method of measurement
Sergeon's decision

5

Description
Arrythemia incidance rate
Timepoint
After the last suture or Mayfield opening till O.R abondonment
Method of measurement
Contineous ECG monitoring

Intervention groups

1

Description
In the case group with last skin suture, infusion of propofol will be ceased but the infusion of remifentanil continued with the half dose of surgery time until response to verbal stimulation by patients.
Category
Prevention

2

Description
In the control group, with the conclusion of surgery both drugs (propofol & remifentanil) will be discontinued and for blinding infusion of normal saline as placebo will starts.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Firouzgar Hospital
Full name of responsible person
Mohammad Reza Ghodraty
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2

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Amir Hossein Bagheri Aghdam MD.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Medicine Faculty, Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhoundzadeh Basti MD.
Street address
Faculty of Medicine, Pour Sina Ave, Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Medicine Faculty, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty