

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

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

Protocol summary

Summary

In a prospective randomized double blind clinical trial, 62 patients with ASA class I-II, undergoing elective supratentorial craniotomy surgery under general anaesthesia using total intravenous anesthesia (propofol and remifentanyl) 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 remifentanyl will be stopped in the control group but maintained in the remifentanyl group with half maintenance dose until extubation. Heart rate (HR), mean arterial pressure (MAP), minogue scale and recovery profiles will be measured and compared 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

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

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 remifentanyl infusion until tracheal extubation on the recovery profile and hemodynamic variables in the patients with elective craniotomy

Public title

Maintaining of remifentanyl 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
Exclusion 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

Postal code**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 sphygmomanometer

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 prevalence 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

Consciousness level

Timepoint

Each 15 minutes until 1 hour in recovery room

Method of measurement

GCS (Glasco coma scale)

4

Description

Reoperation incidence rate

Timepoint

Till 48 hours after operation

Method of measurement

Surgeon's decision

5

Description

Arrhythmia incidence rate

Timepoint

After the last suture or Mayfield opening till O.R abandonment

Method of measurement

Continuous ECG monitoring

Intervention groups

1

Description

In the case group with last skin suture, infusion of propofol will be ceased but the infusion of remifentanyl 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 & remifentanyl) 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

Street address

Department of Anesthesiology, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

2

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Amir Hossein Bagheri Aghdam MD.

Street address

Department of Anesthesiology, Rasoul-e-Akram Hospital, Niayesh St. Sattarkhan Av.

City

Tehran

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amir Hossein Bagheri Aghdam MD.

Position

Anesthesiology Resident

Other areas of specialty/work

Street address

Anesthesiology Department, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8214 1360

Fax

Email

homopersicus@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

m-ghodrati@tums.ac.ir mrghodrati@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

m-ghodrati@tums.ac.ir

Web page address

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