

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation and comparison of intracranial pressure in the patients with supra tentorial tumor According to different the positive end expiatory pressure applied during tumor surgery

Protocol summary

Summary

Aim: The aim of this study is the evaluation of Positive End Expiratory Pressure (PEEP) effect on intracranial pressure (ICP) in the neurosurgical patients with the supratentorial tumor. Method and material: In this clinical trial study, we will be choose 66 patients with the supratentorial tumor who have the indication for the neurosurgical procedure, Inclusion criteria: neurosurgical patients with supratentorial tumor; Ages 18 to 60 years; Without having hypertension or diabetes; No history of stroke or heart failure. Exclusion criteria: patients with lung diseases such as asthma and chronic obstructive pulmonary disease; Brain shifts to the more than 5 mm from the mid line; Severe hydrocephalus; Loss of consciousness; Closed brain solcus, severe headache; Nausea and vomiting. Afterward patients will be divide randomly into 3 groups in PEEP different levels applying that will be include: group A in PEEP=0 cmH2O, group B in PEEP=5 cmH2O and group C in PEEP=10 cmH2O. we will be measure systolic and diastolic blood pressure, mean arterial pressure (MAP) and pulse rate of all patients at different times, also we will be evaluate the consistency of the dura mater before and after dura mater resection. All data and information will be collect and analyze with SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041912782N14**
Registration date: **2017-05-15, 1396/02/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-15, 1396/02/25

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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+98 31 3629 1510

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical sciences.

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of intracranial pressure in the patients with supra tentorial tumor According to different the positive end expiatory pressure applied during tumor surgery

Public title

Effect of Positive End Expiratory Pressure on intracranial pressure in the neurosurgical patients with the supratentorial tumor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: neurosurgical patients with supratentorial tumor; Ages 18 to 60 years; Without having hypertension or diabetes; No history of stroke or heart failure. Exclusion criteria: patients with lung diseases such as asthma and chronic obstructive pulmonary disease; Brain shifts to the more than 5 mm from the mid line; Severe hydrocephalus; Loss of consciousness; Closed brain solcus, severe headache; Nausea and vomiting.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical sciences, Hezar Jareeb street, Isfahan, Iran

City

Isfahan

Postal code

8174675731

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MUI.REC.1395.30320

Health conditions studied

1

Description of health condition studied

supratentorial

ICD-10 code

D33.0

ICD-10 code description

Benign neoplasm: Brain, supratentorial

Primary outcomes

1

Description

Intracranial pressure

Timepoint

Before and after the intervention.

Method of measurement

Touching the dura mater

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group 1: patients who have 0 cmH2O Positive End Expiratory Pressure

Category

Treatment - Devices

2

Description

The intervention group 2: patients who have 5 cmH2O Positive End Expiratory Pressure

Category

Treatment - Devices

3

Description

The intervention group 3: patients who have 10 cmH2O Positive End Expiratory Pressure

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital

Full name of responsible person

Dr Mehrdad Masoudifar

Street address

Alzahra hospital, Alzahra street, Isfahan, Iran

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mansour Siavash

Street address

Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Vahid Salimi

Position

General physician

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Assistant professor of Anesthesiology

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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

