Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of Lung-Protective Ventilation Strategies and on Intraoperative Blood Loss and Surgical Field Quality in Endoscopic Endonasal Transsphenoidal Pituitary Adenoma Surgery: A Randomized Clinical Trial

Protocol summary

Study aim
The aim of this study was to investigate the effect of two mechanical ventilation strategies on the amount of intraoperative bleeding and the quality of the surgical field in patients undergoing endoscopic surgery for pituitary adenoma.

Design
A randomized, single-blind, parallel-group, 1:1 allocation ratio clinical trial study was conducted to compare two mechanical ventilation strategies in patients undergoing endoscopic surgery for pituitary adenoma.

Settings and conduct
This study will be conducted in the operating room of Loghman Hakim Hospital in patients undergoing endoscopic surgery for pituitary adenoma. Eligible patients will be randomly assigned to two ventilation groups after obtaining informed consent and will be evaluated until the end of surgery.

Participants/Inclusion and exclusion criteria
Inclusion: Age ≥18 years, ASA I–II, tumor size, informed consent. Exclusion: Patients with heart failure, severe pulmonary disease, change in surgical plan, coagulation disorders or ongoing blood thinning medication, pregnancy.

Intervention groups
Intervention: Lung protective ventilation (6cc/kg) Control: Conventional ventilation (8cc/kg)

Main outcome variables
Intraoperative bleeding Surgical field quality (Fromme–Boezaart scale)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210415050983N13**
Registration date: **2026-06-14, 1405/03/24**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **0**

Registration date
2026-06-14, 1405/03/24

Registrant information

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Sogol Asgari
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Impact of Lung-Protective Ventilation Strategies and on Intraoperative Blood Loss and Surgical Field Quality in Endoscopic Endonasal Transsphenoidal Pituitary Adenoma Surgery: A Randomized Clinical Trial

Public title
Evaluation of Lung-Protective Ventilation on Intraoperative Bleeding During Endoscopic Pituitary Adenoma Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age >18 ASA I–II tumor size : microadenoma Patient satisfaction
Exclusion criteria:
Patient with heart failure (EF<40%) sever pulmonary disease need to abnormal ventilation uncorrected coagulation disorders or use of blood-thinning medication that have not been discontinued pregnancy Changing the surgical plan or converting to a non-endoscopic procedure Severe hemodynamic instability during surgery requires a change in anesthesia and ventilation protocol. Previous history of pituitary surgery Non-adenomatous tumors of the sellar and parasellar regions
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be assigned to two groups using a 1:1 quadratic block randomization method. The random sequence will be generated by software and stored in sealed, numbered envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be conducted in a single-blind manner, so that the patient and surgeon will not be aware of the assigned ventilation mode, but the anesthesiologist will be aware of the study group due to the need to adjust the ventilation device (anesthesia machine).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Loghman Clinical Research Development Unit
Street address
South Kargar St. - Kamali St. - Special St.
City
تهران
Province
Tehran
Postal code
1333635445
Approval date
2026-05-17, 1405/02/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1405.078

Health conditions studied

1

Description of health condition studied
Skull base tumors are candidates for surgery.
ICD-10 code
D33.2
ICD-10 code description
Benign neoplasm of brain, unspecified

Primary outcomes

1

Description
Intraoperative bleeding
Timepoint
Recorded periodically (every 15–30 minutes) and at the end of surgery.
Method of measurement
Suction volume (ml) minus recorded irrigation volume.Sponges/gauzes: pre-operative dry weight (g) and post-use weight; weight difference converted to ml.

Secondary outcomes

1

Description
Hemodynamic parameters (blood pressure and heart rate).
Timepoint
Every 5–15 minutes.
Method of measurement
Standard monitoring

2

Description
Surgical field of view quality
Timepoint
End of surgery
Method of measurement

Fromme-Boezaart scale

3

Description
Duration of surgery
Timepoint
End of surgery
Method of measurement
Record in the file

4

Description
Need for blood transfusion
Timepoint
During surgery
Method of measurement
Record in the file

Intervention groups

1

Description
Intervention group:Patients will be placed on lung protective ventilation with a tidal volume of 6 cc/kg ideal body weight during general anesthesia.
Category
Treatment - Other

2

Description
Control group: Patients will be ventilated conventionally with a tidal volume of 8 cc/kg ideal body weight during general anesthesia.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
sogol asgari
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South Kargar St. - Kamali St. - Special St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Ziaei
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Velenjak, Yemen Street, Shahid Shahriari Square
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available