Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of pituitary gland function after Endoscopic Transsphenoidal Surgery (ETSS) in pituitary adenoma and corresponding factors in recovery of pituitary function

Protocol summary

Study aim

Evaluation of pituitary gland function after endoscopic transsphenoidal surgery (ETSS) in pituitary adenomas and the factors affecting recovery of gland function. Assessment of the association between the occurrence of pituitary dysfunction after ETSS in pituitary adenomas and the gland's recovery status in relation to tumor pathology, tumor size and invasion, preop pituitary dysfunction, preop hormonal medication usage, and number of surgeries and re-op.

Design

A quasi-experimental study by evaluation before and following patients after ETSS, 3, 6 and 12 months post-op by assessment of hormonal function and MRI of pituitary gland, alongside histopathologic and clinical examination

Settings and conduct

Patients with pituitary adenomas who present to Shariati Hospital and the Dr. Guive Sharifi Pituitary Clinic for surgical treatment will be enrolled in the study after receiving a full explanation of the study conditions and providing informed consent. Preoperative data collected from patients include MRI findings, clinical history focusing on symptoms specific to pituitary tumors, and pituitary hormonal tests alongside relevant paraclinical findings. Patients then undergo surgery (intervention), during which any complication and potential lesion is recorded. The follow-up visits take place 3, 6 and 12 months after surgery, at which tumor histopathology, MRI, updated laboratory tests, and reassessment of clinical symptoms are documented alongside any possible complications.

Participants/Inclusion and exclusion criteria

Candidates of ETSS due to Pituitary Adneoma are enrolled. Any pathology other than PitNET and Pituitary Adenoma are outrolled.

Intervention groups

Candidates of ETSS due to Pituitary Adenoma

Main outcome variables

hypopituitarism (defined as deficiency in at least one pituitary axis) recovery (defined as restoration of function in at least one previously deficient axis).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260430069219N1**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

Yassan Farmani Djamea

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-13, 1403/04/23

Expected recruitment end date

2026-08-20, 1405/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of pituitary gland function after Endoscopic Transsphenoidal Surgery (ETSS) in pituitary adenoma and corresponding factors in recovery of pituitary function

Public title

Pituitary function after ETSS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pituitary Adenoma ETSS Surgery

Exclusion criteria:

Pathology other than Pituitary Adenoma

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Patients who are candidates for ETSS surgery and present to the clinic are enrolled in the study after providing informed consent. Their pituitary function and anatomy are evaluated through laboratory tests and MRI.These assessments are then repeated at 3, 6, and 12 months after surgery, in accordance with international guidelines for postoperative pituitary follow-up. Alongside these, the patient’s overall condition, tumor pathology, medication use, and any potential intraoperative complications are considered together, and their relationships are analyzed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

Poorsina ave., Enghelab Sq.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2024-09-30, 1403/07/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.273

Health conditions studied

1

Description of health condition studied

Pituitary gland function after ETSS in Pituitary Adenoma

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Pituitary Adenoma

ICD-10 code

D35.2

ICD-10 code description

Benign neoplasm of pituitary gland

3

Description of health condition studied

Post-ETSS hypopituitarism

ICD-10 code

E89.3

ICD-10 code description

Postprocedural hypopituitarism

Primary outcomes

1

Description

Incidence of hypopituitarism

Timepoint

3, 6, and 12 months after ETSS surgery

Method of measurement

Pituitary hormonal examination

2

Description

Rate of recovery from hypopituitarism

Timepoint

3, 6, and 12 months after ETSS surgery

Method of measurement
Pituitary hormonal examination

Secondary outcomes

empty

Intervention groups

1

Description
ETSS surgery for Pituitary Adenoma
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Neuroscience Institute
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
Tehran University of Medical Sciences
Full name of responsible person
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Position
Student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No further information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Title and more details about the data/document
Methodology of the study and its results

When the data will become available and for how long
After publication of article

To whom data/document is available
Researchers active in universities and academic centers

Under which criteria data/document could be used
Access to raw and pre-analyzation data other than those published, will not be possible

From where data/document is obtainable
Yassan Farmani Djamea Email address: yasanjame@gmail.com

What processes are involved for a request to access data/document
Sending a fully-explained email and receiving response inside a month-long period

Comments