

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effects of intradural optic canal decompression on the visual outcome in suprasellar meningiomas resection

Protocol summary

Study aim

The effects of intradural optic canal decompression on the visual outcome in suprasellar meningiomas resection

Design

This is a randomized, double-blind clinical trial with parallel groups. Surgery type will be determined using sealed envelopes and divided into two groups of resection with and without intradural decompression of the optic canal. The sample size is 13 patients in each group.

Settings and conduct

This study is performed in Imam Khomeini Hospital. All individuals undergo a fundoscopy one week before surgery to check visual acuity, visual field, and optic nerve status. Tumor size and imaging data will also be recorded. All patients will be hospitalized in the ICU and ward for at least one and 3 days respectively. Any complications during this period will be recorded. After discharge, patients will be referred to Neurosurgery Clinic for follow-up and re-examination one week, one month, and 3 months after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a diagnosis of suprasellar meningioma, candidates for tumor resection who have at least one eye with visual acuity above 0.1 and below 0.7. Exclusion criteria: non-meningioma visual problems, no consent, recurrence of the tumor in the same area, involvement of the optic nerve, major psychiatric disorders, inability to perform MRI

Intervention groups

control group: These patients will undergo craniotomy and mass resection. intervention group: craniotomy and mass resection plus, up to a maximum of 1 cm of canal ceiling will be removed with a surgical drill under a microscopic guide just before the tumor resection begins. Then falciform ligament will open. The eye with lower visual acuity on the examination will be selected for decompression.

Main outcome variables

Visual acuity, visual field, visual complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220319054332N1**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Arad Iranmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2635

Email address

a-iranmehr@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		Blinding description	The study will be double-blinded. Patients are blinded to the type of interventions. Patients will then be coded by one of the study partners and the researcher, outcome evaluator, data analyzer will be blinded to the patient group and the type of intervention.
Scientific title	The effects of intradural optic canal decompression on the visual outcome in suprasellar meningiomas resection	Placebo	Not used
Public title	The effects of intradural optic canal decompression on the visual outcome in suprasellar meningiomas resection	Assignment	Parallel
Purpose	Treatment	Other design features	
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosis of suprasellar meningioma based on clinical examination and imaging findings. Candidates for tumor resection surgery. On visual examination, at least one eye should have a visual acuity above 0.1 and below 0.7. Exclusion criteria: Patients with visual impairment due to damage to the retina, optic nerve, chiasm, or visual cortex for reasons other than suprasellar meningiomas are excluded. Patients who do not agree to continue participating at any stage of the study. Patients who present with tumor recurrence in the same area. Patients who have been diagnosed with a non-meningioma tumor after postoperative pathology report. Patients whose optic nerve is affected by a tumor during surgery Patients with visual acuity below 0.1 in both eyes during the initial preoperative examination. Patients with visual acuity above 0.7 in both eyes during preoperative examinations. Patients with major psychiatric disorders. Patients who do not have adequate access to follow-up at scheduled times. Patients who have a severe reaction to a contrast agent, a metal heart valve, a pacemaker, a non-titanium metal clip, and fear of confinement will not be able to have an MRI.	Secondary Ids	empty
Age	No age limit	Ethics committees	
Gender	Both	1	
Phase	N/A	Ethics committee	
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyzer	Name of ethics committee	Research Ethics Committee of Imam Khomeini Hospital Complex, Tehran University of Medical Sciences
Sample size	Target sample size: 26	Street address	Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
Randomization (investigator's opinion)	Randomized	City	Tehran
Randomization description	Patients are randomly divided into two groups using a sealed envelope and receive the intervention of the same group. The type of surgery is pre-divided evenly on sheets and sealed in special envelopes. After determining the operation time for each patient, one of the envelopes is opened randomly and the type of patient operation is determined based on its contents.	Province	Tehran
Blinding (investigator's opinion)	Double blinded	Postal code	1445983861
		Approval date	2021-01-03, 1399/10/14
		Ethics committee reference number	IR.TUMS.IKHC.REC.1399.386
		Health conditions studied	
		1	
		Description of health condition studied	suprasellar meningiomas
		ICD-10 code	D32.9
		ICD-10 code description	Benign neoplasm of meninges, unspecified
		Primary outcomes	
		1	
		Description	Comparison of the improving the vision of patients with and without intradural decompression of the optic canal after surgery
		Timepoint	3 days, a week, a month, three months after surgery
		Method of measurement	

Snellen chart or Computerized tests

Secondary outcomes

1

Description

Comparison of the incidence of surgical complications of suprasellar meningiomas in patients with and without intradural decompression of the optic canal

Timepoint

Three days after admission to the ward

Method of measurement

Based on history and examinations

Intervention groups

1

Description

Control group: Tumor resection group without intradural decompression of the optic canal

Category

Treatment - Surgery

2

Description

Intervention group: Tumor resection group with intradural decompression of the optic canal

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Arad Iranmehr

Street address

Imam Khomeini Hospital Complex, Tohid Squire

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2636

Email

imamhospital@tums.ac.ir

Web page address

<https://ikhc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Vice Chancellor for Research and Technology, 6th floor, Central University Organization, Felestin St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Arad Iranmehr

Position

Neurosurgery resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Neurosurgery department, Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone
00982161190
Fax
Email
a-iranmehr@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Arad Iranmehr
Position
Clinical Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Neurosurgery ward, Imam Khomeini hospital, Tohid sq., Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2635
Fax
Email
a-iranmehr@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Arad Iranmehr
Position
Clinical Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address

Neurosurgery ward, Imam Khomeini hospital, Tohid sq., Tehran

City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2635
Fax
Email
a-iranmehr@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Clinical data, treatment outcomes, radiological and ophthalmic findings, and demographic data

When the data will become available and for how long

The access period starts 10 months after the results are published

To whom data/document is available

public

Under which criteria data/document could be used

Detailed study information can be provided to qualified researchers interested in treating patients.

From where data/document is obtainable

corresponded author of article

What processes are involved for a request to access data/document

Competent and enthusiastic researchers can obtain data documents after the publication of the work from the corresponded author by providing academic information and identification.

Comments