Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of therapeutic effect of nimodipine on facial nerve injury following cerebellar peduncle angle tumor surgery

Protocol summary

Study aim
Evaluation of therapeutic effect of nimodipine on facial nerve injury following cerebellopeduncular angle tumor surgery

Design
The subjects will be placed on the first day of postoperative post-PO surgery and will be allowed to start feeding or gavage under the semi-mediastin with g60 every 6 hours. The first fallopian is 3 times and then 6 months after the surgery. The recovery pattern of the facial nerve is based on House-Brackmann Score and will be evaluated and recorded.

Settings and conduct
The study will be conducted as a blind clinical trial. The site of the study will be Imamreza Hospital.

Participants/Inclusion and exclusion criteria
Patients with CPA tumor in Tabriz Imam Reza Hospital will undergo surgery in the neurosurgery department and will be operated in the lateral position and with the retro-sigmoid approach. People who have a clear cut of nerves during surgery will be excluded from the study.

Intervention groups
Intervention group: The subjects will be placed on the first day of postoperative post-PO surgery and will be allowed to start feeding or gavage under the condition of norepinephrine with g60 every 6 hours. The first fallopian is 3 times and then 6 months after the surgery.

Main outcome variables
The recovery pattern of the facial nerve is based on House-Brackmann Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120527009878N8**
Registration date: **2019-06-12, 1398/03/22**
Registration timing: **prospective**
Last update: **2019-06-12, 1398/03/22**
Update count: **0**

Registration date
2019-06-12, 1398/03/22

Registrant information

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Firooz Salehpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effect of nimodipine on facial nerve injury following cerebellar peduncle angle tumor surgery

Public title
Evaluation of therapeutic effect of nimodipine on facial nerve injury following brain tumor surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient with CP angle tumor with diameter less than 3 cm and postoperative facial weakness Satisfaction to participate in the study
Exclusion criteria:
Facial weakness before surgery Complete nerve disruption during surgery Large tumor diameter (over 3 cm) Tumors other than schwannoma and meningioma

Age
To **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz university of medical sciences
Street address
Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street.
City
Tabriz
Province
East Azarbaijan
Postal code
04133357310
Approval date
2019-05-20, 1398/02/30
Ethics committee reference number
IR.TBZMED.REC.1398.201

Health conditions studied

1

Description of health condition studied
Faintal nerve weakness after surgery
ICD-10 code
S04.5
ICD-10 code description
Injury of facial nerve

Primary outcomes

1

Description
The recovery pattern of the nasal fascia
Timepoint
After discharge from the operating room, 3 and 6 months after surgery
Method of measurement
House-Brackmann Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Subjects will be placed on the first day of postoperative post-PO surgery and will be allowed to start feeding or gavage under the semi-mediastin with g60 every 6 hours. The first fallopian is 3 times and then 6 months after the surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurosurgery Ward of Emem Reza hospital
Full name of responsible person
Mohammad Kazemzadeh Yaghouti Nobar
Street address
Imamreza Hospital, Daneshgah Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Mohammad Kazemzadeh Yaghouti Nobar

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Ali Meshkini

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

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Position
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Latest degree
Medical doctor

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Neurosurgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Study data is accessible by observing moral points of view on the confidentiality of patient information.

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

To whom data/document is available
Neuropsychiatric specialists in coordination with the presenter

Under which criteria data/document could be used
The use of data to improve patients' treatment processes is safe

From where data/document is obtainable
Person responsible for updating study information

What processes are involved for a request to access data/document
Requesting data and study documents will be done by correspondence with the person responsible for updating the study information.

Comments