Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of preoperative single dose intravenous dexamethasone in decreasing the postparotidectomy facial nerve dysfunction rate in patients with benign superficial lobe of parotid tumor

Protocol summary

Summary

In this clinical trial that will be unicentric, 40 Patients with benign parotid tumor with normal facial function and without deep parotid lobe involvement, will be selected and divided randomly and in double blind manner into two 20 person groups of drug (dexamethasone injection) and placebo (normal saline injection). Four hours before the parotid surgery, 8 mg of intravenous dexamethasone will be injected in patients of drug group and 2 ml of normal saline will be injected intravenously in patients of control (placebo) group. Then, all patients will undergo superficial parotidectomy. In the postoperative period, the efficacy of preoperative single dose intravenous dexamethasone in decreasing the facial nerve dysfunction rate and its relationship with the size, location and type of the tumor will be evaluated. In the case of nerve palsy, the nerve recovery time and the involved branches will be examined in both drug and placebo groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060823594N2**
Registration date: **2016-07-12, 1395/04/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-12, 1395/04/22

Registrant information

Name

Mehrnoush Mousavi-Aghdas

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of preoperative single dose intravenous dexamethasone in decreasing the postparotidectomy facial nerve dysfunction rate in patients with benign superficial lobe of parotid tumor

Public title

The efficacy of preoperative single dose intravenous dexamethasone in decreasing the postparotidectomy facial nerve dysfunction rate in patients with benign superficial lobe of parotid tumor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with benign parotid tumor and

normal facial nerve function Exclusion criteria: patients with history of diabetes mellitus; history of autoimmune diseases; sensitivity to corticosteroids and other contraindications of these medicines; history of corticosteroid use; tumor spread to deep lobe; history of previous surgery of the parotid; history of face and neck radiotherapy; history of malignant disease in parotid gland and face; and preoperative facial nerve dysfunction in each branch

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabrizl University of Medical Sciences Ethics Committee

Street address
Tabriz University of Medical Sciences, Daneshgah street, Tabriz, Iran

City
Tabriz

Postal code

Approval date
2016-06-07, 1395/03/18

Ethics committee reference number
ir.tbzmed.rec.1395.165

Health conditions studied

1

Description of health condition studied
Facial nerve dysfunction

ICD-10 code
SO4.5

ICD-10 code description
Injury of facial nerve

Primary outcomes

1

Description
Facial nerve dysfunction

Timepoint
First day, one week and one month after the surgery

Method of measurement
Physical exam

Secondary outcomes

1

Description
Involved branches of facial nerve

Timepoint
First day, one week and one month after the surgery

Method of measurement
Physical exam

2

Description
Size of tumor

Timepoint
After surgery

Method of measurement
Lab

3

Description
Histologic type of tumor

Timepoint
After surgery

Method of measurement
Lab

4

Description
Position of tumor

Timepoint
During surgery

Method of measurement
Visual

Intervention groups

1

Description
Eight milligrams of intravenous dexamethasone injection in the patients of drug (intervention) group 4 hours before the parotidectomy

Category

Treatment - Drugs

2

Description
Two milliliters of normal saline intravenous injection in the patients of placebo (control) group 4 hours before the parotidectomy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
ENT (Otolaryngorhinology) Department, Imam Reza Hospital
Full name of responsible person
Dr. Kasra Tavassoli
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohamad Reza Rashidi
Street address
Tabriz University of Medical Sciences, Daneshgah street, Tabriz, Iran
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Tabriz
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
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
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Person responsible for scientific inquiries

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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

Data Dictionary

empty