

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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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Tabriz University of Medical Sciences

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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**

Tabriz 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

S04.5

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Kasra Tavassoli

Position

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Other areas of specialty/work

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Other areas of specialty/work

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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