

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation the effectiveness of botulinum toxin injection in improving the complication of Sialoceles after parotidectomy

Protocol summary

Study aim

Determining the effectiveness of botulinum toxin injection in improving the complication of sialoceles after parotidectomy

Design

The clinical trial will have a control and intervention group, in parallel and double-blind, randomized by a simple randomization method using a closed envelope and a phase 2-3 clinical trial study on 100 patients.

Settings and conduct

A study was conducted on 100 patients referred to the clinic of Qaim Hospital in Mashhad, who were prescribed partial parotidectomy, they would be placed in the intervention and control groups in a parallel and double-blind trial (participant, evaluator) during Surgery after parotidectomy botulinum toxin injection will be performed in the intervention group and pressure dressing of the remaining complications will be performed in the control group, and the effect of this intervention on the swelling of the fistula and sialoceles after surgery will be investigated.

Participants/Inclusion and exclusion criteria

Informed consent to enter the project and diagnosis of tumor in the parotid lobe, as well as benign pathological results in fine needle aspiration before surgery, no Botox in the last 3 months, and no sensitivity or allergic reaction to Botox are the main conditions for entering the study.

Intervention groups

In the intervention group, during parotidectomy surgery, 30 up to 40 units of diluted botulinum toxin will be injected deeply in multi areas based on the amount of remaining parotid tissue, but in the control group, during parotidectomy surgery, routine treatment will be performed according to its procedure and in the remaining area of the parotid tissue only pressure bandaged will be done.

Main outcome variables

Swelling of the fistula and sialoceles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210923052559N2**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Farzaneh Iravani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3723 1750

Email address

farzaneh.baroon@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-14, 1401/11/25

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of botulinum toxin injection in improving the complication of Sialoceles after parotidectomy

Public title

Investigating the effect of botulinum toxin on parotidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tumor located in the superficial parotid lobe Benign pathological results in preoperative fine needle aspiration Full consent to enter the study

Exclusion criteria:

Facial paralysis before surgery History of Botox in the last 3 months Allergy or allergic reaction to Botox Pregnancy Breastfeeding History of spastic cerebral palsy Suffering from all types of severe respiratory failure

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be done by www.randomization.com website . Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study subjects and those who evaluate the outcome will be unaware of the intervention and control groups. Of course, written consent is obtained from the patients, at the same time, the patients do not know what substance was used during the surgery, and the researcher evaluating the outcome does not know which group the patients belong to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.464

Health conditions studied

1

Description of health condition studied

Neoplasm of parotid gland

ICD-10 code

D11.0

ICD-10 code description

Benign neoplasm of parotid gland

Primary outcomes

1

Description

Swelling of the fistula and sialoceles

Timepoint

Before the start of the intervention and 48 hours after surgery and the use of botulinum toxin

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients of this group who have undergone partial parotidectomy surgery and during surgery a 500 cc vial is diluted with 2.5 cc of normal saline, each 0.5 cc of normal saline contains 100 units of Mesport and from this solution with this concentration is injected, the amount of botulinum toxin, which can vary between 30 and 40 units depending on the amount of remaining tissue from the parotid, is injected deeply in

three to four areas of the remaining tissue from the parotid during surgery.

Category

Treatment - Drugs

2

Description

Control group: In the control group, surgery is performed according to the routine procedure, and in the remaining area of the parotid tissue, only compression dressing is performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Kamran khazayeni

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2649

Email

khazaenik@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayour Mobarhan

Street address

Central Building of Mashhad University of Medical Sciences (Ghoreyshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Kamran khazayeni

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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City

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Person responsible for updating data

Contact

Name of organization / entity
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9176699199
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available