Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Superficial parotidectomy with or without the use of a post-operative drain: A Randomized, Open-label, Phase II Clinical Trial

Protocol summary

Study aim
Evaluation of postoperative complications and length of hospital stay in patients with and without drain placement

Design
This is a phase II, randomized, controlled clinical trial involving 70 patients. Participants are allocated to study groups using a simple randomization method.

Settings and conduct
This study is conducted on patients undergoing superficial parotidectomy at this hospital, and postoperative complications are monitored during the follow-up period.

Participants/Inclusion and exclusion criteria
Participants include patients diagnosed with benign parotid neoplasm who candidates for superficial parotidectomy. Exclusion criteria consist of patients with malignant parotid tumors and those with underlying coagulation disorders.

Intervention groups
The intervention group consists of patients who undergoing superficial parotidectomy without drain placement, whereas the control group consists of patients who undergoing superficial parotidectomy with drain placement.

Main outcome variables
The primary outcome is the rate of postoperative surgical site complications (hematoma, seroma, and infection) within the first 60 days post-surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260511069350N1**
Registration date: **2026-05-25, 1405/03/04**
Registration timing: **registered_while_recruiting**
Last update: **2026-05-25, 1405/03/04**
Update count: **0**

Registration date
2026-05-25, 1405/03/04

Registrant information

Name
Rezvan Salimi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 77 2768 4226

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31

Expected recruitment end date
2027-05-21, 1406/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Superficial parotidectomy with or without the use of a post-operative drain: A Randomized, Open-label, Phase II Clinical Trial

Public title
Superficial parotidectomy with or without the use of a post-operative drain: A Randomized, Open-label, Phase II Clinical Trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with benign salivary gland tumors located in the superficial lobe of the parotid gland

Exclusion criteria:

malignant tumor Hemostatic disorders

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was performed using a random numbers table to allocate participants to the intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasoul Akram Hospital, Sattarkhan St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1461614745

Approval date

2026-01-30, 1404/11/10

Ethics committee reference number

IR.IUMS.REC.1404.977

Health conditions studied

1

Description of health condition studied

Comparison of the incidence of postoperative complications after superficial parotidectomy for benign parotid neoplasms with versus without drain placement.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The incidence rate of postoperative hematoma

Timepoint

within a 2-month postoperative period

Method of measurement

The diagnostic criterion is clinical assessment, and ultrasound will be used if necessary.

Secondary outcomes

1

Description

Postoperative seroma formation rate.

Timepoint

within a 2-month postoperative period

Method of measurement

The diagnostic criterion is clinical assessment, and ultrasound will be used if necessary.

Intervention groups

1

Description

Intervention group: Patients undergoing superficial parotidectomy without drain placement.

Category

Treatment - Surgery

2

Description

Control group: Patients undergoing superficial parotidectomy with drain placement.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Rezvan Salimi

Street address

Rasoul Akram Hospital, Sattarkhan Street, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
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Rasoul Akram Hospital, Sattarkhan Street, Tehran, Iran.
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Rezvan Salimi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable
Title and more details about the data/document
Information related to the primary outcome and study results.
When the data will become available and for how long
Data access will commence 6 months after publication of the results.
To whom data/document is available
Access will be restricted to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
Data may be used for non-commercial academic research, including secondary analyses and meta-analyses, under a data use agreement ensuring confidentiality and proper citation of the original trial.
From where data/document is obtainable
rezvansalimi805@gmail.com
What processes are involved for a request to access data/document
The request for data use must be submitted in writing, accompanied by a brief research proposal and an analysis plan, to the principal investigator. Following scientific and ethical review and approval, and upon signing a data use agreement, de-identified data will be made available to the applicant within the scope of that agreement.
Comments