

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 77 2768 4226

###### Email address

salimi.re@iums.ac.ir

##### 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.

##### City

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rezvansalimi805@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Majid Safa  
**Street address**  
Rasoul Akram Hospital, Sattarkhan Street, Tehran,  
Iran.  
**City**  
Tehran  
**Province**  
Tehran  
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rezvansalimi805@gmail.com  
**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

Ear, Nose, and Throat

#### Street address

Rasoul Akram Hospital, Sattarkhan Street, Tehran,  
Iran.

#### City

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#### Province

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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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**