

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The study of changes on function of eustachian tube after balloon tuboplasty on patients with resistant serous otitis media

Protocol summary

Summary

Objective: The effectiveness of balloon tuboplasty in improvement of eustachian tube function in patients with eustachian tube dysfunction Design: clinical trial Setting and conduct: All patients with serous otitis media resistant to medical therapy in amiralam hospital receive balloon tuboplasty surgery Major inclusion and Exclusion criteria: Inclusion criteria: some patients with 18-60 years age; some patients with resistant serous otitis media; some patients with recurrence of symptoms after ventilation tube replacement. Exclusion criteria: some patients with past history of nasopharyngeal tumor; some patients with high risk for general anesthesia; some patients with history of systemic diseases. Intervention: Case group: in 20 patients with serous otitis media resistance to therapy after audiometric tests and endoscopy ,surgery will be done. At first the catheter entered to cartilage eustachian tube and fill with saline with 10 bar pressure and the balloon refill after second minute and the catheter extrude. Control group: No control group Main outcome measures(variables): The treatment of hearing loss

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015091524031N1**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Mojtaba Mohammadi Ardehali

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of changes on function of eustachian tube after balloon tuboplasty on patients with resistant serous otitis media

Public title

Evaluation result of balloon tuboplasty on patients with serous otitis media

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 18-60 years old patients; patients with resistant serous otitis media; patients with recurrence of symptoms after ventilation tube replacement. Exclusion

criteria: patients with past history of nasopharyngeal tumor; patients with high risk for general anesthesia; patients with history of systemic diseases.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods Street, Keshavarz Boulevard

City

Tehran

Postal code

1417653761

Approval date

2015-10-13, 1394/07/21

Ethics committee reference number

IR.TUMS.REC.1394.954

Health conditions studied

1

Description of health condition studied

Serous Otitis

ICD-10 code

H65.9

ICD-10 code description

Nonsuppurative otitis media, unspecified

Primary outcomes

1

Description

Recovery of eustachian tube function

Timepoint

Before surgery and 1 week after surgery and 3 month and 6 month after surgery

Method of measurement

Valsalva maneuver and R Index and audiometry

Secondary outcomes

1

Description

Improvement in hearing

Timepoint

1 week after surgery and 3 month and 6 month after surgery

Method of measurement

Tympanometry and PTA test and ETT test

Intervention groups

1

Description

Intervention group: 20 patients with serous otitis media resistance are undergoing balloon tuboplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam Hospital

Full name of responsible person

Dr Mojtaba Mohamadi Ardehali

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AmirAlam Hospital, North Saadi Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

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Central Organization of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

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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
Vice Chancellorfor Research, Tehran 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
Tehran university of Medical Sciences

Full name of responsible person
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Position
Otolaryngologist

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