Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 gerenal 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 catteter entered to cartilage eustachian tube and fill with salin with 10 bar pressur and the balloon refill after second minute and the catteter 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

Tehran University of Medical Sciences

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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
Befor 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
Typmanometery 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

Street address
AmirAlam Hospital, North Saadi Avenue

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellorfor 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

City
Tehran
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
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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