

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of audiometric and histologic results in crushed cartilage tympanoplasty and non crushed :a Randomized clinical trial study

Protocol summary

Summary

The purpose of this study is comparison of the audiometric and histological results of crushed cartilage tympanoplasty with non crushed cartilage tympanoplasty, in a randomized clinical trial. Patients with the indication for cartilage tympanoplasty divide to two groups with randomized blocking method. we have 20 patients in each group. during the surgery we prepare cartilage graft from concha cavum, in the first group we crush the cartilage slightly and place it on the graft of fascia with the underlying method. In the second group (control) the cartilage places uncrushed. For the patients with the indication of ossiculoplasty at this step we do tympanoplasty and the ossicle reconstruction operates 1 year later. the patients will be examined and do audiometric tests every 4 months for 1 year. we will prepare biopsy from the cartilage graft. Patients with the indication of ossiculoplasty (1 year later). it will be investigate for the features like chondrocytes viability and the connective tissue features. inclusion criteria: patients with the indication of cartilage tympanoplasty there is not any age and sex limitations at least 1 year follow up exclusion criteria: previous canal wall down (CWD) revision surgery history of chondritis (polychondritis &...) patients with adhesive otitis conductive and sensoryneural hearing threshold, the tympanic membrane condition and the cartilage graft will be studied and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013132069N3**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Ardavan Tajdini

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 3037

Email address

a-tajdini@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr Yunesian, Vice chancellor for research, Tehran University of Medical Sciences, The Central Department, 6th floor, Qods st, Keshavarz blv, tel: 00982188987381-2 www.tums.ac.ir/research, email: resdeputy@tums.ac.ir

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of audiometric and histologic results in crushed cartilage tympanoplasty and non crushed :a Randomized clinical trial study

Public title

Results of using crushed cartilage in tympanoplasty

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: there is not any age and sex limitations
patients with the indication of cartilage tympanoplasty at
least 1 year follow up exclusion criteria: previous canal
wall down (CWD) revision surgery history of chondritis
(polychondritis &...) patients with adhesive otitis

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Tehran University of
Medical Sciences

Street address

Central Department Of University, 6th floor,
Keshavarz blv, Qods st-

City

Tehran

Postal code

Approval date

2017-01-28, 1395/11/09

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1550

Health conditions studied

1

Description of health condition studied

Chronic perforation of tympanic membrane

ICD-10 code

H72

ICD-10 code description

perforation of ear drum: persistent post-traumatic
postinflammatory

Primary outcomes

1

Description

audiometric condition

Timepoint

before the surgery, every 4 months after surgery upto 1
year

Method of measurement

audiometric test and determin the hearing treshold in
different frequencies

2

Description

tympanic mambrane condition

Timepoint

before the surgery, every 4 months after surgery upto 1
year

Method of measurement

physical examination and tympanometry

Secondary outcomes

1

Description

superior posterior tympanic retraction

Timepoint

1 year after surgery

Method of measurement

microscopic examination

2

Description

pars flaccida retraction

Timepoint

1 year after surgery

Method of measurement

microscopic examination

3

Description

sensoryneural hearing treshold

Timepoint

before the surgery and 1 year after surgery

Method of measurement

Audiometry

4

Description

conductive hearing treshold

Timepoint

before the surgery and 1 year after surgery

Method of measurement

audiometry (db)

5

Description

cartilage graft condition

Timepoint

1 year after surgery

Method of measurement

biopsy and staining

Intervention groups

1

Description

Intervention group : using crushed cartilage for tympanoplasty

Category

Treatment - Surgery

2

Description

Control group: non crushed cartilage tympanoplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Aalam Hospital

Full name of responsible person

Dr Nikou Hatami

Street address

Darvaze Dolat, Saadi st, Enqelqb st

City

Tehran

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

Street address

Central Department of University, 6th floor, Qods st, Keshavarz blv

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for 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 Science

Full name of responsible person

Dr Nikou Hatami

Position

ENT Resident

Other areas of specialty/work

Street address

Amir Alam Hospital, Darvaze Dolat, Saadi st, Enqelab st

City

Tehran

Postal code

Phone

+98 21 6670 6106

Fax

Email

nikouhatami@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University Of Medical Science

Full name of responsible person

Dr Ardavan Tajdini

Position

ENT professor

Other areas of specialty/work

Street address

Darvaze Dolat, Saadi st, Engelab st

City

Tehran

Postal code

Phone

+98 21 6670 6106

Fax

Email

ardavan_taj@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University Of Medical Science, Amir Aalam
Hospital

Full name of responsible person

Dr Nikou Hatami

Position

ENT Resident

Other areas of specialty/work**Street address**

Darvaze Dolat, Enqelqb st, Saadi st-

City

Tehran

Postal code**Phone****Fax****Email**

Nikouhatami@gmail.com

Web page address

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