Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of postoperative results of cochlear implantation with round window and cochleostomy approach in patients undergoing cochlear implant

Protocol summary

Summary

There are different methods in the world for cochlear implantation such as(cochleostomy or round window) in children with auditory problems. Each method improve patient's speech or hearing abilities vie specific mechanism. There are a lot of experimental or clinical trial studies about the role of different methods on children's speech or hearing abilities while there's not enough evidences in comparison of these methods together. The goal of this study is comparing the effect of two surgical methods of cochlear implantation on patient's function after surgery This study is a clinical trial that is designed to comparison the results of cochleostomy and round window methods during 2015 till 2016. All patients who are candidate for cochlear implantation in Pediatric Hospital of Tabriz, take part in this study. All participants randomly divided in two groups. The first group composed of patients under cochleostomy surgery while patients in second group will undergo round window surgery. All patients will be examined by two types of test after surgery. First is speech intelligibility rating test and the other is Categories of Auditory Performance test. All patient's information will be recorded and compare between two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121531429N1**
Registration date: **2017-01-31, 1395/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-31, 1395/11/12

Registrant information

Name
Yalda Jabbarimoghadam

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 914 161 3913

Email address
jabbariy@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date
2015-10-23, 1394/08/01

Expected recruitment end date
2017-01-20, 1395/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of postoperative results of cochlear implantation with round window and cochleostomy approach in patients undergoing cochlear implant

Public title

Comparison of postoperative results of cochlear implantation with round window and cochleostomy approach in patients undergoing cochlear implant

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients which are candidate for cochlear implant; patients admitted to Pediatric Hospital of Tabriz exclusion criteria: patients with post surgery complications; coexisting diseases affected on auditory system.

Age

To **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

all patients who are cochlear implantation surgery, will be divided randomly in two study groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences, Faculty of Medicine, Department of Otolar

Street address

Tabriz University of Medical Science, Daneshgah avenue, Tabriz,East Azerbaijan

City

Tabriz

Postal code

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.TBZMED.REC.1395.2.25

Health conditions studied

1

Description of health condition studied

cochlear implantation

ICD-10 code

H80,H83

ICD-10 code description

Other specified diseases of inner ear

Primary outcomes

1

Description

Speech Intelligibility

Timepoint

45-60 days after surgery then very three months to one year

Method of measurement

Speech Intelligibility Rating

2

Description

Auditory Performance

Timepoint

45-60 days after surgery then very three months to one year

Method of measurement

Categories of Auditory Performance

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1: surgery with Cochleostomy

Category

Treatment - Surgery

2

Description

intervention group 2: surgery by Round Window method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children's Hospital

Full name of responsible person

Dr.Masood Naderpour

Street address

Tabriz Children's Hospital, Sheshgelan street

City

Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr.Masood Naderpour
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
City
Tabriz
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 of Tabriz 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
Department of Otolaryngology of Tabriz University of Medical Sciences
Full name of responsible person
Dr.Masood Naderpour
Position
phd/professor
Other areas of specialty/work
Street address
Department of Otolaryngology, Imam Reza Hospital, Golgasht Street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 3335 2076
Fax
Email
info@imamreza.tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Otolaryngology, Tabriz University of Medical Sciences
Full name of responsible person
Dr.Masood Naderpour
Position
PHD.
Other areas of specialty/work
Street address
Department Otolaryngology, Imam Reza hospital, Golgasht street, Tabriz
City
Tabri
Postal code
Phone
+98 41 3335 2076
Fax
Email
info@imamreza.tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Science
Full name of responsible person
Zohreh Amini
Position
Medical Doctor
Other areas of specialty/work
Street address
Department Otolaryngology, Imam Reza hospital, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 3335 7310
Fax
Email
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