

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Calculation of the Correlation between mean of puretone audiometry(PTA) thresholds and mean of auditory steady state responses(ASSR) thresholds in 10 normal hearing adults

Protocol summary

Summary

Objective: To prepare an objective tool for measuring hearing thresholds in stead of puretone audiometry which can reduce subject`s role in measuring hearing thresholds. Design: To find an objective test as a replacement for PTA, the correlation between the thresholds measured by PTA and an objective test should be measured. In this study the objective test is auditory steady state responses. For this reason in this study at first we measured PTA thresholds and ASSR thresholds in each octave frequency in the study group and then the correlation between the tow thresholds have been measured. Setting: The study group was selected accidently from the people who came to rehabilitation faculty of Tehran University of Medicines. At the first step the subjects were asked about the history of different disease, any ear brunt, ear disease, vertigo or other disequilibrium, ear pain and hearing loss. Then subjects are tested through basic hearing tests includes otoscopic inspection, immittance evaluation and acoustic reflex evaluation. Measuring hearing thresholds by PTA and ASSR in subjects who no abnormality were seen in their tests were conducted and then the correlation between these tow thresholds is measured to understand whether ASSR can be used in stead of PTA. Participant: Participants in this study includes 10 adult woman aging 18-29 years old who were selected from who came to rehabilitation faculty of Tehran University of Medicines. After selecting this group, basic hearing tests were conducted and abnormal subjects were role out from study. Intervention: Basic hearing tests were conducted in this group and after that puretone audiometry and auditory steady state responses has been conducted in this group. To measure ASSR thresholds golden electrodes were placed on forehead and mastoid process. Main outcome: At the end and after measuring PTA and ASSR thresholds, the correlation between tow

thresholds will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108157337N1**

Registration date: **2011-11-23, 1390/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-23, 1390/09/02

Registrant information

Name

Fateme Shayan

Name of organization / entity

Tehran University Of Medical science

Country

Iran (Islamic Republic of)

Phone

+98 33 1262 3417

Email address

f_shayan3500@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Calculation of the Correlation between mean of puretone audiometry(PTA) thresholds and mean of auditory steady state responses(ASSR) thresholds in 10 normal hearing adults

Public title
Comparision between mean of auditory steady state responses(ASSR) thresholds and mean of puretone audiometry (PTA) thresholds in 10 normal hearing adults

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion: 1- Age range through 18-30 2-Without any history of hearing disease or any other health problems 3-Without any wax in ear canal 4-Without any abnormality in ear canal or tympanic membrane 5- Without any abnormality in middle ear measurment 6- Present of acoustic rerflex in normal intensity range
Exclusion: 1-PTA threshold is out of normal range 2- ASSR results is not useful

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

1
Registry name
Comparision between mean of auditory steady state responses(ASSR) thresholds and mean of puretone audiometry (PTA) thresholds in 10 normal hearing adults

Secondary trial Id
90-02-61-12878

Registration date
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Tehran University Of Medical science
Street address
Research Center of Markaze Roshde Estedadhaye Derakhshan-16 azar avenue-enghelab avenue- Tehran
City
Tehran
Postal code
Approval date
2011-05-28, 1390/03/07
Ethics committee reference number
1336/130/90

Health conditions studied

1
Description of health condition studied
Normal Hearing
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
PTA Threshold
Timepoint
1 week
Method of measurement
puretone audiometry(dBHL)

2
Description
ASSR Threshold
Timepoint
1 week
Method of measurement
auditory steady state response test(dBHL)

Secondary outcomes

empty

Intervention groups

1
Description
Performing puretone audiometry and auditory steady state responses
Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Faculty of Tehran University Of Medical science (Mirdamad Faculty)

Full name of responsible person

Fateme Shayan

Street address

Nezam Alley-Shahnazari Street-Mirdamad Stree

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Management System, Tehran University of Medical Science

Full name of responsible person

Mrs. Alamdar

Street address

Sixth floor, Main building of Tehran University Of Medical Sciences, 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

Research Management System, Tehran University of Medical Science

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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Full name of responsible person

Fateme Shayan

Position

Bachelor of Science in audiology

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

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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