

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of propofol-remifentanil and sevoflurane effects on stapedius reflex in children undergoing cochlear implant surgery

Protocol summary

Summary

The aim of this study is to compare the effect of anesthesia with sevoflurane and propofol-remifentanil on stapedius reflex in children undergoing cochlear implant surgery. A total of 36 children, aged 6 months to 7 years, ASA I-II, involving severe or complete neural hearing loss undergoing cochlear implant surgery in children's hospital will be allocated into two groups. The anesthesia will be maintained with infusion of remifentanil-propofol in one group and sevoflurane in the other group. Both groups will receive O₂-N₂O in concentration of 50%-50% for maintenance of anesthesia. After induction of anesthesia, bispectral index will be used for monitoring the level of anesthesia and will be maintained in 50±10 limit. Morphine, 0.1 mg/kg, will be administered for postoperative pain in group 1, 15-30 minute before termination of surgery. Stapedius reflex and hemodynamic changes will be compared during anesthesia and recovery room between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104026022N3**

Registration date: **2011-05-07, 1390/02/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-07, 1390/02/17

Registrant information

Name

Reza Taheri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2250

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-05-01, 1390/02/11

Expected recruitment end date

2012-11-01, 1391/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propofol-remifentanil and sevoflurane effects on stapedius reflex in children undergoing cochlear implant surgery

Public title

Effects of anesthetics on stapedius reflex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children with severe to profound sensory neural hearing loss who are candidate for cochlear implant surgery Exclusion criteria: Children with a history of adverse reaction to any study drug

Age

To **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

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

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Ave,

City

Tabriz

Postal code

Approval date

2010-10-16, 1389/07/24

Ethics committee reference number

5/4/5447

Health conditions studied

1

Description of health condition studied

Anesthesia

ICD-10 code

Y48.0

ICD-10 code description

Anaesthetics and therapeutic gases

Primary outcomes

1

Description

Stapedius reflex

Timepoint

evaluation is done while testing

Method of measurement

by Nucleus Freedom cochlear implant device

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

every 10 minutes during anesthesia

Method of measurement

by electrocardiography and blood pressure measurement

Intervention groups

1

Description

Intervention group will receive remifentanyl (0.2-0.5mcg/kg/min) + propofol (100-150mcg/kg/min) during 4 hours anesthesia

Category

Treatment - Drugs

2

Description

Control group will receive 2-3% MAC sevoflurane through the ventilator, during 4 hours anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children hospital of Tabriz

Full name of responsible person

Reza Taheri

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Alireza ostad rahimi

Street address

Tabriz University of Medical Sciences, Daneshgah Avenue

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
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
Children hospital of Tabriz
Full name of responsible person
Reza Taheri
Position
Anesthesiologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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