Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Recruitment status
Recruitment complete
Funding source
Tabriz University of Medical Siences

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 divice

Secondary outcomes

1

Description
Hemodynamic changes
Timepoint
every 10 minutes during anesthesia
Method of measurement
by electrocardiography and blood pressure measurment

Intervention groups

1

Description
Intervention group will receive remifentanil (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
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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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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