

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 O<sub>2</sub>-N<sub>2</sub>O 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

taherireza@tbzmed.ac.ir

##### 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**

**Street address**

Children hospital of Tabriz, Sheshgelan avenue

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1526 2250

**Fax**

**Email**

dr.reza.taheri@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Children hospital of Tabriz

**Full name of responsible person**

Reza Taheri

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Children hospital of Tabriz, Sheshgelan avenue

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1526 2250

**Fax**

**Email**

dr.reza.taheri@gmail.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Children hospital of Tabriz

**Full name of responsible person**

Reza Taheri

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

**City**

Tabriz

**Postal code**

**Phone**

+98 914 102 4249

**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*