Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

the comparison effect of propofolel and sevoflurane on the QT interval prolongation in pediatrics undergoing cochlear implantation

Protocol summary

Summary

purpose : the comparison effect of propofolel and sevoflurane on the QT interval prolongation in pediatrics undergoing cochlear implantation methods : in this randomized controlled clinical trial 64 patients aged 6 months to 18 years, candidate for cochlear implantation were enrolled . known case of jervell lange nielson syndrome , pations with any cardiac disease, ECG abnormalitie, electrolyte abnormalitie, usage of drags which prolong the QT interval and family history of QT prolongation, were excluded for the study . 1 hours before enterance of the patients to the operating room midazolam was administrated 0.5 - 0.75 mg/kg orally and 0.05 - 0.1 mg/kg intravenously . 12 leads ECG was applied and baseline strips were taken for all participant . fentanyl 2 ug/kg was administrated premedication . using the random number table patients were divided to 2 groups ; group A who received sevoflurane with standard mac induction and group B who received propofole (2.5 mg/kg) . 5 and 15 minutes after drug administration ECG was performed and evaluated for QT prolongation and other abnormalities between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082131487N2**
Registration date: **2017-10-16, 1396/07/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-16, 1396/07/24

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

iran medicine science university

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the comparison effect of propofolel and sevoflurane on the QT interval prolongation in pediatrics undergoing cochlear implantation

Public title

the comparison of ECG changes propofole and sevoflurane cochlear implantation

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion critria : patients aged 6 months to 18years condidate for cochlear implantation . exclusion critria: known case of jervell lange nielson syndrome , patients with any cardiac disease, ECG abnormalitie, electrolyte abnormalitie, usage of drags which prolong the QT

interval and family history of QT prolongation .

Age
From **6 months** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
iran university of medical sciences
Street address
iran university of medical sciences , hemmat highway
City
tehran
Postal code

Approval date
2017-05-06, 1396/02/16

Ethics committee reference number
IR.IUMS.REC1396.9311174019

Health conditions studied

1

Description of health condition studied
cochlear implantation

ICD-10 code
DISEASES O

ICD-10 code description
other specified diseases of inner ear(h83.8(

Primary outcomes

1

Description
QT INTERVAL

Timepoint
AFTER THE INDACTION

Method of measurement
ECG MONITORING AND CALCULATED BY THE CARDIOLOGIST

Secondary outcomes

1

Description
PROLONGET TP-E INTERVALL

Timepoint
5 AND 15 MINIUTE AFTER DRAG ADMINISRATION

Method of measurement
ECG MONITORING AND CALCULATED BY CARDIOLOGIST

Intervention groups

1

Description
Intervention Group1:2.5mg/kg propofol for induction

Category
Treatment - Drugs

2

Description
Intervention Group2:sevofeloran with mac 8% for induction

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
rasool akram hospital
Full name of responsible person
DR.reza safaeeian
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sattar-khan avn
City
tehran

2

Recruitment center
Name of recruitment center
rasool akram hospital
Full name of responsible person
DR.reza safaeeian
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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
iran university of medical sciences
Full name of responsible person
DR.alireza poornajafiand
Street address
firozgar haspital
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
iran university of medical sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
iran university of medical sciences
Full name of responsible person
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Street address
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City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
iran university of medical sciences
Proportion provided by this source
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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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