

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The comparison of the effect of ondansetron and dexamethason on QT interval prolongation in pediatrics undergoing cochlear implantation

#### Protocol summary

2017-05-10, 1396/02/20

##### Summary

Purpose: Pediatrics candidate for cochlear implantation often need surgery at an early age. Administration of antiemetic drugs cause complications such as QT prolongation. Therefore we designed this study to evaluate the effect of drugs applied on QT prolongation. Methods: In this randomized controlled clinical trial 60 patients aged 6 months to 18 years, candidate for cochlear implantation were enrolled. Known cases of jervell lange nielson syndrome and patients with cardiac complications, ECG and electrolytes abnormalities, those who used drugs which caused QT prolongation and with family history of QT prolongation, were excluded from the study. 1 hour before the entrance of the patients to the operating room midazolam was administered 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 administered as premedication. Sevoflurane 8% and atracorium (0.5mg/kg) was used for induction. Isoflurane 1.2% was applied as maintenance. Using the random number table patients were divided to 2 groups; group A who received dexamethasone (0.1mg/kg) and group B who received ondansetron (0.2 mg/kg). 5 and 15 minutes after drug administration ECG was performed and evaluated for QT prolongation and other abnormalities between groups.

##### Registrant information

###### Name

مهرداد Mesbah kiaei

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 346 5866

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##### Recruitment status

###### Recruitment complete

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the effect of ondansetron and dexamethason on QT interval prolongation in pediatrics undergoing cochlear implantation

##### Public title

The comparison of ECG changes of ondansetron and dexamethasone in cochlear implantation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 6 months to 18 years

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122031487N1**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

candidate for cochlear implantation. Exclusion criteria: Known case of jervell lange nielson syndrome; patients with any cardiac disease; ECG abnormalities; electrolyte abnormalities; usage of drugs 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: **60**

#### 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

Ethics committee of Iran university of medical sciences

##### Street address

school of Medicine, Iran university of medical sciences, Hemmat Highway

##### City

Tehran

##### Postal code

#### Approval date

2017-03-01, 1395/12/11

#### Ethics committee reference number

IR.IUMS.REC 1395.9311174024

## Health conditions studied

### 1

#### Description of health condition studied

long QT syndrom

#### ICD-10 code

I45.8

#### ICD-10 code description

Other specified conduction disorders

## Primary outcomes

### 1

#### Description

Prolonged QT interval

#### Timepoint

5 and 15 minutes after drug administration

#### Method of measurement

ECG monitoring and calculated by the cardiologist

## Secondary outcomes

### 1

#### Description

Vomit

#### Timepoint

After the surgery

#### Method of measurement

inspection

### 2

#### Description

Nausea

#### Timepoint

After the surgery

#### Method of measurement

inspection

### 3

#### Description

Prolonged Tp-e interval

#### Timepoint

5 and 15 minutes after drug administration

#### Method of measurement

ECG monitoring and calculated by the cardiologist

## Intervention groups

### 1

#### Description

Intervention Group 1: Ondansetron( 0.2 milligram per kilogram)

#### Category

Treatment - Drugs

### 2

#### Description

Intervention Group2: Dexamethason (0.1 milligram per kilogram)

#### Category

Treatment - Drugs

### 3

#### Description

Control Group: Patient's baseline ECG before

administration of drugs  
**Category**  
Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Rasool Akram hospital, Satarkhan street, Tehran  
**Full name of responsible person**  
Dr Reza Safaeian  
**Street address**  
**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr Reza Safaeian  
**Street address**  
School of Medicine, Iran university of medical sciences, Hemmat Highway  
**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

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**  
Rasool Akram Hospital  
**Full name of responsible person**  
Dr Reza Safaeian  
**Position**  
Associate Professor  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Rasool Akram Hospital  
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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*