Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Dexmedetomidine, Dexamethasone and Metoclopramide for prevention of postoperative Nausea and Vomiting after Tympanomastoidectomy

Protocol summary

Summary

We are comparing the effect of Dexmedetomidine and Dexamethasone and Metoclopramide, for prevention of nausea and vomiting in Tympanomastoidectomy surgery. We are going to enroll all patients who have elective Tympanomastoidectomy surgery and are sedated by general anesthesia that referred to Amirkabir hospital and have inclusion criteria. In this study we don't use placebo and it's double blind and randomized cases. We will measure and record the Heart rate and mean arterial Blood pressure and Blood Oxygen saturation, before the surgery for all patients and take ECG for all of them. In all groups, 10 minutes after tracheal intubation, interventional drugs will be administered [Dexmedetomidine (dexmed) 1 mg/ kg / IV in group A, Dexamethasone (dexa) 8 mg / IV in group B and Metoclopramide (meto) 10 mg / IV in group C that their volume increased to 4 ml by Saline.] The research assistant who knows nothing about our classification, will prepare the drugs and code.(double-blind) At different times of operation [before administering interventional drugs (T0), at 5 minutes after administering (T1), at 30 minutes after administering (T2), at 5 minutes after extubation (T3), at the time of entrance to recovery room(T4)], we will measure blood pressure and Heart rate. At the first 24 hours after operation (every 6 hours), We will evaluate the patient's nausea and vomiting. The score of Nausea and Vomiting will be recorded. If score of nausea in one patient is more than 60 (according to VAS score) or if he/she asks antiemetic drugs, We will provide him or her with 4 ml Ondansetron and that time will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092629993N1**
Registration date: **2017-03-23, 1396/01/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-23, 1396/01/03

Registrant information

Name

Atefeh Khalifeh

Name of organization / entity

Arak University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3639

Email address

rafeie@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Dexmedetomidine, Dexamethasone and Metoclopramide for prevention of postoperative Nausea and Vomiting after Tympanomastoidectomy

Public title
Effect of Dexmedetomidine for prevention of postoperative Nausea and Vomiting
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: All adult patients at the age of 20-50 years; Patients with ASA class I -II; absence of drug abuse and Opioid addiction; Patients who fulfil Apfel criteria. Exclusion criteria: being allergic to drugs under study; Using of antiemetic drugs 48 hours before operation for any reason; BMI up to 35 kg / m2; pregnancy; not willing to participate in the study.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Payambar Azam University complex, Basij square, Arak.
City
Arak
Postal code
38481-7-6941
Approval date
2016-01-18, 1394/10/28
Ethics committee reference number
IR.ARAKMU.REC.1394.281

Health conditions studied

1

Description of health condition studied
Complications of General Anesthesia.
ICD-10 code
T88.8
ICD-10 code description
Other specified complications of surgical and medical care, not elsewhere classified.

Primary outcomes

1

Description
Nausea and Vomiting
Timepoint
First 24 hours post Operation (every 6 houre).
Method of measurement
Ask from the Patient based on the VAS score.

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before prescribing intervener Drugs (T0), At 5 minutes after prescribing (T1), At 30 minutes after prescribing (T2), At 5 minutes after Extubation (T3), At the time of enterance to recovery (T4).
Method of measurement
By Sphygmomanometer, mmHg.

2

Description
Pulse rate
Timepoint
Before prescribing intervener Drugs (T0), At 5 minutes after prescribing (T1), At 30 minutes after prescribing (T2), At 5 minutes after Extubation (T3), At the time of enterance to recovery (T4).
Method of measurement
Counting in one minute.

3

Description
O2 Saturation
Timepoint
Before Operation.
Method of measurement
Pulse Oximetery.

Intervention groups

1

Description
Intervention group 1: In group A (dexmed) 1 mcg / Kg Dexmedetomidine will be prescribed intravenously (IV), 10 minutes after tracheal intubation . Its volume will be increased to 4 ml using Normal Saline.
Category
Prevention

2

Description
Intervention group 2: In group B (Dexa) 8 mg / IV Dexamethasone will be prescribed intravenously (IV), 10 minutes after tracheal. Its volume will be increased to 4 ml using Normal Saline.
Category
Prevention

3

Description
Intervention group 3: In group C (Meto) 10 mg / IV Metoclopramide will be prescribed intravenously (IV), 10 minutes after tracheal. Its volume will be increased to 4 ml using Normal Saline.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital
Full name of responsible person
Doctor Hesamodin Modir
Street address
Amir Kabir Hospital, Rah Ahan square, Arak.
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Doctor Mohammad Rafeie
Street address
Payambar Azam University complex, Basij square, Arak.
City
Arak
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak 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
Arak University of Medical Sciences
Full name of responsible person
Doctor Hesamodin Modir
Position
Anesthesiologist
Other areas of specialty/work
Street address
Vali-ye-Asr Hospital, Vali-ye-Asr square, Arak.
City
Arak
Postal code
3814957558
Phone
-
Fax
-
Email
he_modir@arakmu.ac.ir
Web page address
-

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Doctor Esmaiel Moshiri
Position
Anesthesiologist
Other areas of specialty/work
Street address
Vali-ye-Asr Hospital,vali-ye-Asr square, Arak.
City
Arak
Postal code

3814957558

Phone

+98 86 3224 1411

Fax

-

Email

he_modir@arakmu.ac.ir

Web page address

-

3848176941

Phone

-

Fax

-

Email

at.kh89@gmail.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Atefeh khalifeh

Position

General practitioner

Other areas of specialty/work

Street address

Payambar Azam University Complex, Basij Square, Arak.

City

Arak

Postal code

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