

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of premedication in anesthesia and hemodynamic Dexmedetomidine cataract surgery with local anesthesia and sedation with propofol applied topically

Protocol summary

Summary

Aim of this study is effect of premedication in anesthesia and hemodynamic Dexmedetomidine cataract surgery with local anesthesia and sedation with Propofol applied topically. This study is a double blind clinical trials. 100 patients with cataract surgery will enter to study. We will divide patients in two groups randomly. We will inject 0.5 microgram per kilogram Dexmedetomidine in intervention group. We will inject normal saline in control group. We will record vital sign before injection of Dexmedetomidine or normal saline and before induction of anesthesia with Propofol and every 5 minute during surgery. We will record time of awake in patients at the end of surgery. Inclusion criteria: patients with cataract surgery; 45 to 70 years; ASA class I and II. Exclusion criteria: kidney disease; cardiovascular disease; hepatic disease; pulmonary disease; chronic use narcotic and drug and neurological drugs

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050120258N43**
Registration date: **2017-05-04, 1396/02/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research , Arak University of Medical Sciences

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of premedication in anesthesia and hemodynamic Dexmedetomidine cataract surgery with local anesthesia and sedation with propofol applied topically

Public title

Effect of premedication in anesthesia and hemodynamic Dexmedetomidine cataract surgery with local anesthesia and sedation with propofol applied topically

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with cataract surgery; 45 to 70 years; ASA class I and II Exclusion criteria: kidney disease; cardiovascular disease; hepatic disease; pulmonary disease; chronic use narcotic and drug and

neurological drugs

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Arak University Of Medical Sciences

Street address
Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht, Arak

City
Arak

Postal code
38149578558

Approval date
2016-02-15, 1394/11/26

Ethics committee reference number
IR.ARAKMU.REC.1394.292

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Senile cataract

Primary outcomes

1

Description
Vital sign

Timepoint
before Induction of anesthesia with Propofol and every 5 minute during surgery

Method of measurement
Device

2

Description
time awake patient

Timepoint
in end of surgery discontinuation of Propofol

Method of measurement
minute

Secondary outcomes

empty

Intervention groups

1

Description
control group:We inject normal saline .

Category
Treatment - Drugs

2

Description
Intervention group: We inject 0.5 microgram per kilogram Dexmedetomidine, 10 minute before start surgery in intervention group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital

Full name of responsible person
Dr Bijan Yazdi

Street address
Amirkabir hospital, Parastar 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
 Dr Mohammad Rafiee
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 Vice chancellor for research, Payambar Azam
 Complex, Basij square, Sardasht, 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
 Dr Hesamodin Modir
Position
 Faculty, Anesthesiologist
Other areas of specialty/work
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Person responsible for updating data

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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