Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of oral clonidine premedication on postoperative pain and agitation following cataract surgery under general anesthesia

Protocol summary

Study aim
Reduction of postoperative pain and restlessness following cataract surgery.
Design
62/5000 Clinical trial with community-based control and randomized control group
Settings and conduct
Shahrood Imam Hosein hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female, 18 – 70 years old ASA class 1&2&3(, risk of anesthesia) Exclusion criteria: A history of drug abuse, antihypertensive therapy, antidepressant, anticonvulsive, beta blocker, Fluvoxamine, digoxin, dextromethorphan and every complication during surgery or anesthesia
Intervention groups
Patients are randomly divided into two equal treatment groups: placebo(control) or group A and clonidine or group B with simple randomized method.
Main outcome variables
postoperative pain & agitation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170213032560N2**
Registration date: **2018-07-30, 1397/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-30, 1397/05/08**
Update count: **0**
Registration date
2018-07-30, 1397/05/08

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 935 621 4141
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kalantari@shmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-10-11, 1395/07/20
Expected recruitment end date
2018-08-04, 1397/05/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of oral clonidine premedication on postoperative pain and agitation following cataract surgery under general anesthesia

Public title
Assessment of oral clonidine premedication on postoperative pain and agitation following cataract surgery under general anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18-85 years ASA class 1& 2 & 3
Exclusion criteria:
Exclusion criteria: A history of drug abuse, antihypertensive therapy, antidepressant, anticonvulsive, beta blocker, Fluvoxamine, digoxin, dextromethorphan and every complication during

surgery or anesthesia

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

According to randomized quadruple blocks, researcher gives a predetermined series of 70 A and B cards to the ophtalomology ward nurse who is responsible for blinding of trial. Based on this pattern participants will assign in to either intervention (A) and take clonidine or control (B) group that take placebo one hour before operation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Questionnaire has two parts with identical cod. Ophthalmology ward nurse, who is responsible for randomization and blinding of research, enclose the second part of questionnaire (post operative pain chart) to the patient medical record file.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Deputy of research, Shahroud University of Medical Sciences

Street address

Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square, Shahroud, Iran Shahroud

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2016-07-05, 1395/04/15

Ethics committee reference number

IR.SHMU.REC.1395.114

Health conditions studied

1

Description of health condition studied

H25.0 Senile incipient cataract H57.1 ocular pain

ICD-10 code

H57.1

ICD-10 code description

Ocular pain

2

Description of health condition studied

H25.0 Senile incipient cataract H57.1 ocular pain

ICD-10 code

H25.0

ICD-10 code description

Age-related incipient cataract

Primary outcomes

1

Description

Pain, burning, foreign body sensation in the eye

Timepoint

15min 30min 45min 60min 1h 2h 3h 4h 12h 18h 24h after operation

Method of measurement

Researcher uses 0-10 numeric pain rating scale for assessment of postoperative pain.

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, participant takes oral clonidine (Tablet 0.2 mg manufactured by Tolidaru corporation) with 30ml water one hour before operation. Ophthalmology ward nurse who is responsible for randomization supervises this procedure.

Category

Treatment - Drugs

2

Description

Control group: In controll group the patiens take 30 ml water with placebo one hour before operation. Ophthalmology ward nurse who is responsible for randomization supervises this procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital, End of Ayatollah Towhidi avenue, Shahroud, Iran

Full name of responsible person
mahsa kalantari

Street address
Deputy Dean for research, Shahroud University of Medical Sciences, 7th of Tir square, Shahroud, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
mohammad hasan emamian

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Seventh Tir Square - Shahrood University of Science and Technology - Vice Chancellor for Research

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emamian@shmu.ac.ir

Web page address
http://shmu.ac.ir/research/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahroud University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
mahsa kalantari

Position
medical intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
all of the writers don't agree with it
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available