

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Email address

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 ophthalmology 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

City

shahroud

Province

Semnan

Postal code

4571984315

Phone

+98 23 3239 5054

Email

mahsa.kalantari92@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

mohammad hasan emamian

Street address

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

City

shahrood

Province

Semnan

Postal code

36147-73947

Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

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

Street address

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

City

shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

mahsa.kalantari92@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

mahsa kalantari

Position

medical intern

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Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

mahsa.kalantari92@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

mahsa kalantari

Position

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Latest degree

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General Practitioner

Street address

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

City

shahrood

Province

Semnan

Postal code

45719-84315

Phone

+98 24 3552 5589

Email

mahsa.kalantari92@yahoo.com

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