Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of melatonin and acetaminophen on pain and hemodynamic alterations associated with retrobulbar eye block in cataract surgery

Protocol summary

Summary

The aim of this study is comparison of melatonin and acetaminophen on pain and hemodynamic alterations associated with retrobulbar eye block in cataract surgery. After taken an informed consent, 180 patients scheduled for cataract surgery with (ASA-PS)I-III will be recruited in a double-blinded randomized trial(neither patients&researcher know treatment). The patients will be classified to 3 groups. Inclusion criteria: patients aged 50-90 years with(ASA-PS)I- III ,scheduled for elective cataract surgery. Exclusion criteria: coagulopathy; ongoing treatment with anti coagulant drugs ;Cognition disorders; Alzheimer's disease ;allergy to local anesthetic drugs ;Claustrophia ;chronic cough ; narcotics and opioids addiction; sedative drug users ; Surgeries under general anesthesia ;surgical duration more than one hour and failure of retrobulbar block patients will take melatonin 6 mg (melatonin group) , acetaminophen 500 mg (acetaminophen group) and placebo(placebo group) orally 60 min before arrival in the operating room .Fentanyl 0.5 µg/kg IV is administered before the retrobulbar block. Hemodynamic variables (HR،SBP،DBP،MAP،O2 Sat)are measured .Score of pain is recorded according to the VAS before and 1 min after block ,5 min after and end of operation ,and in the recovery room. Complications like nausea, vomiting, low oxygen saturation level are noted and treated. Fentanyl 0.5 µg/kg will be administered IV during the surgery if the patients complain of pain with VAS more than 3.Data will be recorded in a questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012315963N4**
Registration date: **2015-03-11, 1393/12/20**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-03-11, 1393/12/20

Registrant information

Name
Soudabeh Haddadi
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13332383068
Email address
so_haddadi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice-chancellor for Research of Guilan University

Expected recruitment start date

2015-04-19, 1394/01/30

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of melatonin and acetaminophen on pain and hemodynamic alterations associated with retrobulbar eye block in cataract surgery

Public title

Comparison of melatonin and acetaminophen in cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Patients aged 50-90 years with(ASA-PS)I- III ,scheduled for elective cataract surgery Exclusion criteria:coagulopathy; ongoing treatment with anti coagulant drugs ;Cognition disorders; Alzheimer's disease ;allergy to local anesthetic drugs ;Claustrophia ;chronic cough ; narcotics and opioids addiction; sedative drug users ; surgeries under general anesthsia ;surgical duration more than one hour and failure of retrobulbar block

Age

From **50 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences, Parastar St., Rasht, IRAN

City

Rasht

Postal code

Approval date

2015-01-05, 1393/10/15

Ethics committee reference number

1930474206

Health conditions studied

1

Description of health condition studied

cataract

ICD-10 code

H25.9

ICD-10 code description

Senile cataract, unspecified

Primary outcomes

1

Description

pain

Timepoint

before and 1 min after block ,5 min after and end of operation ,and in the recovery room

Method of measurement

visual analog scale

2

Description

O2 saturation

Timepoint

before and 1 min after block ,5 min after and end of operation ,and in the recovery room

Method of measurement

pulse oxymetery

3

Description

heart rate

Timepoint

before and 1 min after block ,5 min after and end of operation ,and in the recovery room

Method of measurement

vital signs monitoring device

4

Description

mean arterial pressure

Timepoint

before and 1 min after block ,5 min after and end of operation ,and in the recovery room

Method of measurement

vital signs monitoring device

Secondary outcomes

1

Description

nausia,vomitting

Timepoint

during retrobulbar block ,surgery and recovery

Method of measurement

Obsevation

2

Description

low oxygen saturation level

Timepoint
during retrobulbar block ,surgery and recovery
Method of measurement
vital signs monitoring device

Intervention groups

1

Description
Placebo group will take placebo pill with water orally 60 min before arrival in the operating room
Category
Placebo

2

Description
Melatonin group will take 6 mg melatonin pill with water orally 60 min before arrival in the operating room
Category
Treatment - Drugs

3

Description
Acetaminophen group will take 500 mg acetaminophen pill with water orally 60 min before arrival in the operating room
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-Almomenin hospital
Full name of responsible person
Drs Sodabeh Haddadi
Street address
Rasht
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
vice-chancellor for Research
Street address
Guilan University of Medical Sciences, Parastar St., Rasht,Iran
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Science
Full name of responsible person
Drs Sodabeh Haddadi
Position
Anesthesiologist
Other areas of specialty/work
Street address
Amir-Almomenin Hospital, Guilan University of Medical Sciences, Rasht, Iran
City
Rasht
Postal code
Phone
+98 13 3323 8307
Fax
Email
So_Haddadi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Drs Sodabeh Haddadi
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Web page address

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