

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effect of cryo therapy on pain scores and contentment of patients in cataract surgery under topical anesthesia

Protocol summary

Summary

The study is carried out as a one-center randomized clinical trial on 80 patients being at the age of 55 to 75 years old and candidate for cataract surgery in Velayat hospital of Qazvin province. Patients with abusers, Cold Intolerance and pharmaceutical mydriasis less than 5 mm are excluded. Patients randomly (using closed envelopes and choose A or B cards) are divided into two groups (intervention and control). Intervention: in the intervention group (cryo therapy), after the arriving of patients to the operating room, gel eye mask (cold in the refrigerator at 4 ± 2 ° C) for 5 minutes will be put on the eyes. Local anesthesia will be performed for all patients with similar method. In both groups, Tropicamide, Xylocaine and balanced salt solution (BSS) will be used, with the difference that in the intervention group all medications in a refrigerator (4 ± 2 ° C temperature) and cooled. All patients will be without stitches. Vancomycin is an antibiotic used to prevent endophthalmitis. In the case of VPS > 4, the patient is treated with fentanyl 1 mg/kg during surgery. Systolic and diastolic blood pressure and heart rate will be measured at baseline, before of induction, 5, 10, 15, 30, 45 and 60 minutes after surgery, score of pain at 15, 30 and 60 after surgery, Postoperative complications and Patients satisfaction After entering the recovery are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052734091N2**

Registration date: **2017-07-08, 1396/04/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-08, 1396/04/17

Registrant information

Name

Matina Majdi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3376 0620

Email address

m.majdi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cryo therapy on pain scores and contentment of patients in cataract surgery under topical anesthesia

Public title

Effect of cryo therapy on pain scores and contentment of patients in cataract surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients 55 to 75 years old; candidate

surgery of cataract; consent to participate up to the end study. Exclusion criteria: Need to inject propofol during surgery; opium addiction; psychotropic and analgesic drugs receivers; history of intraocular surgery; history of intraocular inflammatory diseases; other eye diseases; Pharmaceutical Mydriasis less than 5 mm; Cold Intolerance.

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients randomly (using closed envelopes and choose A or B cards) are divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comittee of Qazvin University of Medical Sciences

Street address

Shahid Bamonar Blvd, Qazvin.

City

Qazvin

Postal code

3419759811

Approval date

2017-04-18, 1396/01/29

Ethics committee reference number

IR.QUMS.REC.1396.12

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H26.9

ICD-10 code description

Cataract, unspecified

Primary outcomes

1

Description

postoperative pain

Timepoint

At 15, 30, 45 and 60 minutes after surgery

Method of measurement

Score of pain in verbal pain score (VPS)

2

Description

Systolic blood pressure

Timepoint

At baseline, before of induction, 5, 10, 15, 30, 45 and 60 minutes after surgery

Method of measurement

Monitoring devise

3

Description

Diastolic blood pressure

Timepoint

At baseline, before of induction, 5, 10, 15, 30, 45 and 60 minutes after surgery

Method of measurement

Monitoring devise

4

Description

Heart rate

Timepoint

At baseline, before of induction, 5, 10, 15, 30, 45 and 60 minutes after surgery

Method of measurement

Pulse Oxymetry

Secondary outcomes

1

Description

Postoperative complications(Headache, nausea and vomiting, shivering, respiratory depression)

Timepoint

After entering the recovery

Method of measurement

Questions from patient

2

Description

Patients satisfaction

Timepoint

After entering the recovery
Method of measurement
Questions from patient

Intervention groups

1

Description

In intervention group: after the arriving of patients to the operating room, gel eye mask (cold in the refrigerator at $4 \pm 2^{\circ}\text{C}$) for 5 minutes will be put on the eyes and all medications in a refrigerator ($4 \pm 2^{\circ}\text{C}$ temperature) and cooled.

Category

Prevention

2

Description

In control group: Cold gel eye mask will not be used and Medications are not put in the refrigerator.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat educational and treatment center

Full name of responsible person

Dr. Matina Majdi

Street address

Velayat hospital, Taavon square, 22 Bahman Blvd, Minoodar, Qazvin.

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Shahid Bahonar Blvd, Qazvin.

City

Qazvin

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 Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Matina Majdi

Position

Assistant of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University Of Medical Sciences

Full name of responsible person

Dr.Marzieh Beigom Khezri

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Person responsible for updating data

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Position

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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