

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation the effect of topical prednisolon acetate 1% on the pupillary diameter and ocular pain after uncomplicated cataract surgery in diabetic and non diabetic patients

Protocol summary

Study aim

To assess the effect of pre-operative prednisolone acetate 1% on maintenance of intra-operative mydriasis and post-operative pain in uncomplicated cataract surgery in diabetic and non-diabetic patients: a randomized trial.

Design

This clinical trial (phase 3) consists of 4 groups: 2 interventions and 2 controls. Intervention 1 or A were non-diabetic patients who received prednisone 1% eye drop, control 1 or B were non-diabetic patients who received artificial tears as placebo. Intervention 2 or C were non-diabetic patients who received prednisone 1% eye drop, control 2 or D were non-diabetic patients who received artificial tears as placebo. Patients' randomization was performed by the table of random numbers. sample size was 80 (20 participants in each group).

Settings and conduct

This prospective study is conducted on patients over 40 years of age with cortical cataract, posterior subcapsular, or nuclear sclerosis, which are characterized by general anesthesia phacoemulsification surgery in Khatam al-Anbia (PBUH) Hospital

Participants/Inclusion and exclusion criteria

In diabetic and non-diabetic group: Inclusion criteria: Patients over 40 years old with cortical cataract, posterior subcapsular or grade 2 to 3 nuclear sclerosis with indication of phacoemulsification surgery under general anesthesia; Exclusion criteria: Previous history of intraocular surgery; collagen vascular diseases; mature cataract; History of or current use of non-steroid drugs, alpha-blocker, anti-glycemic drugs; ; History of Uveitis

Intervention groups

Non-Diabetic patients: group A received prednisone acetate 1% topical eye drop, group B received artificial tear drop as placebo. Diabetic patients: group C

received prednisolone acetate 1% topical eye drop and group D used artificial tear drop as placebo.

Main outcome variables

pupil size; pain, photophobia; itching; foreign body sensation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038617N1**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Abolfazl Hoseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-13, 1395/12/23

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

Evaluation the effect of topical prednisolon acetate 1% on the pupillary diameter and ocular pain after uncomplicated cataract surgery in diabetic and non diabetic patients

Public title

Effect of prednisolon acetate drop on pupil dilation and ocular pain after cataract surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

In non- diabetic group: Patients over 40 years old with cortical cataract, posterior subcapsular or grade 2 to 3 nuclear sclerosis that have indication of phacoemulsification surgery with general anesthesia
In diabetic group: Patients over 40 years old with cortical cataract, posterior subcapsular or grade 2 to 3 nuclear sclerosis that have pseudoexfoliation or non proliferative diabetic retinopathy and have indication of phacoemulsification surgery with general anesthesia

Exclusion criteria:

History of previous intraocular surgery collagen vascular disease history of previous or current topical steroids, alfablocker or antiglaucoma medication history of previous or current systemic steroid use history of uveitis mature cataract

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

If non-diabetic patients have inclusion criteria, they will be divided in to 2 groups of A and B through simple random sampling and using envelopes. Also, diabetic patients that have inclusion criteria will be divided in to 2 groups of C and D through simple random sampling and using envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in control group were given placebo which its appearance was the same as the medication which was administered for intervention group. All participants, researcher, surgeons and outcome investigator were blind about the medication were used for each patient.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Khatamolania Hospital, Gharani street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2017-01-28, 1395/11/09

Ethics committee reference number

IR.MUMS.fm.REC.1395,119

Health conditions studied**1****Description of health condition studied**

Effect of topical dipped prednisolone acetate 1% on pupil dilatation and pain after uncomplicated cataract surgery

ICD-10 code

H25.0

ICD-10 code description

Age-related incipient cataract

Primary outcomes**1****Description**

Horizontal pupillary diameter

Timepoint

The diameter of the pupillary horizontal diameter is measured at the beginning and at the end of the operation using caliber and is divided into two groups up and down six millimeters.

Method of measurement

Caliber

2

Description

The score of post-operative pain which is measured by Visual Analog Scale for pain questionnaire.

Timepoint

24 hours after surgery

Method of measurement

Score of Visual Analog Scale for pain questionnaire

Secondary outcomes

1

Description

post operative photophobia

Timepoint

24 hours after surgery

Method of measurement

Visual Analogue Scale for pain questionnaire

2

Description

Foreign body sensation

Timepoint

24 hours after surgery

Method of measurement

Visual Analogue Scale for pain questionnaire

3

Description

Itching

Timepoint

24 hours after surgery

Method of measurement

Visual Analogue Scale for pain questionnaire

Intervention groups

1

Description

Intervention 1: Non-diabetic patients who receive topical prednisone acetate 1% drop, every six hours, 24 hours before surgery. Patients are advised to shake the bottle before using. The administered drop is produced by Sinadaroo company.

Category

Prevention

2

Description

Intervention group: Diabetic patients who receive topical prednisone acetate 1% every six hours, 24 hours before surgery. Patients are advised to shake the bottle before using. The administered drop is produced by Sinadaroo company.

Category

Prevention

3

Description

Control group1: Non-Diabetic patients who receive preservative- free artificial tears every six hours, 24 hours before surgery. The administered drop is produced by Sinadaroo company.

Category

Placebo

4

Description

Control group2: Diabetic patients who receive preservative- free artificial tears every six hours, 24 hours before surgery. The administered drop is produced by Sinadaroo company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al-anbya hospital

Full name of responsible person

Hamid Gharaee

Street address

Gharani blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Email

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Grant name

Research deputy of Mashhad University of Medical Sciences

Grant code / Reference number

941814

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Hoseinzadeh Abolfazl

Position

Residence

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data of patients and research result are shareable after undetectabing of patient since 2019

When the data will become available and for how long

From 2019

To whom data/document is available

Researchers of academic center only

Under which criteria data/document could be used

Clinical and practical usage is okay

From where data/document is obtainable

Email: Hoseinzadea1@mums.ac.ir Tel: 00989122276382

What processes are involved for a request to access data/document

Send an email to Hoseinzadeha1@mums.ac.ir

Comments