Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

T o 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 perforemed 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 nucleic 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 prednisolne 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)

Phone

+98 51 3840 8480

Email address

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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 acetete 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 pseudoexfuliation 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, alphablocker 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
Khatamolanbia 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 pupilary diameter
Timepoint
The diameter of the pupilary 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 recieve 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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Mashhad
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Postal code
9195965919
Phone
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Email
Gharaee_oph@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamidreza Gharaee
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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

Street address
No23,Besat ave.,Ahmadabad Blvd.

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Position
Residence

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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)
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 undetectabling of patient since 2019

When the data will become available and for how long

From2019

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