

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of tropicamide 0.5% and tropicamide 1% on intraocular pressure, pupil size, keratometry and anterior chamber parameters in patients with type 1 and type 2 diabetes mellitus

Protocol summary

Study aim

To compare the effect of tropicamide 0.5% and tropicamide 1% on intraocular pressure and anterior chamber parameters in patients with Diabetes Mellitus

Design

Clinical trial with parallel groups, double-blinded, randomized, phase 3 on 210 patients.

Settings and conduct

Patients with diabetes type 1 and type 2 older than 21 years of age, in the specialized clinic of Kowsar Hospital (Semnan University of Medical Sciences) are examined. Eligible individuals enter the study and are randomly assigned to group 1 or group 2. In each group, visual acuity measurement, slit lamp biomicroscopy and fundus examination are performed. Intraocular pressure is measured with Goldmann applanation tonometer. pupil size, refraction and keratometry are measured with two different autorefractometers. keratometry, pupil size and other anterior chamber parameters are also evaluated by Oculus Pentacam imaging. Then, the patients receive tropicamide 0.5% drops in group 1 and tropicamide 1% drops in group 2. 30 minutes later, all previous measurements are repeated. Patients and the ophthalmologist and the data analyzer are unaware of the drug type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Diabetes Mellitus type 1 and 2, older than 21 years old; Exclusion criteria: Proliferative diabetic retinopathy, history of cataract surgery, severe nuclear and cortical cataract, glaucoma, intraocular pressure (IOP) greater than 21 mmHg, familial history of glaucoma, narrow angle (Van Herick 1, 2), iris neovascularization, pregnancy, corneal dystrophy and ectasia, pterygium, keratorefractive surgery, Iris disorders, miotics or mydriatics use

Intervention groups

Intervention group 1: This group receives tropicamide

0.5% drops. Intervention group 2: This group receives tropicamide 1% drops.

Main outcome variables

Intraocular pressure (IOP); pupil diameter

General information

Reason for update

The study has been completed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200829048553N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **1**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Navid Elmi Sadr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

2021-07-07, 1400/04/16

Actual recruitment end date

2021-11-07, 1400/08/16

Trial completion date

2021-11-07, 1400/08/16

Scientific title

Comparison of the effect of tropicamide 0.5% and tropicamide 1% on intraocular pressure, pupil size, keratometry and anterior chamber parameters in patients with type 1 and type 2 diabetes mellitus

Public title

Effect of tropicamide 0.5% vs tropicamide 1% on intraocular pressure of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Diabetes Mellitus type 1 and 2

Exclusion criteria:

Proliferative diabetic retinopathy History of cataract surgery severe nuclear and cortical cataract Glaucoma Intraocular pressure (IOP) greater than 21 mmHg Familial history of glaucoma Narrow angle (Van Herick 1, 2) Cup to disc ratio greater than 0.5 Pregnancy Pterygium Corneal ectasia History of keratorefractive surgery Corneal dystrophy Iris disorders Anisocoria Iris neovascularization Use of miotics or mydriatics

Age

From **21 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **210**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization: In this study, the randomized block method is used to allocate the participants into two groups. Each block will have 4 units (2 units related to intervention group and 2 units related to comparison group). There will be 6 different combinations of intervention and comparison in each block. Using the computer-generated random numbers, one of the combinations is selected. In this way, patients are balanced into two groups of intervention and comparison.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drops are instilled into the patients' eye by a nurse. Study participants are unaware of the type of medication used. The outcome assessor (ophthalmologist) does not know the type of medication used for each patient. The data is analyzed by a biostatistician. He or she also does not know the type of drug used for each patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

www.ClinicalTrials.gov

Secondary trial Id

NCT04932213

Registration date

2021-06-07, 1400/03/17

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

Ethics committee of semnan university of medical sciences

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran

City

semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.SEMUMS.REC.1400.018

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2**Description of health condition studied**

Type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Intraocular pressure (IOP)

Timepoint

Before intervention, 30 minutes after intervention

Method of measurement

Goldmann applanation tonometry

2

Description

Pupillary diameter

Timepoint

Before intervention, 30 minutes after intervention

Method of measurement

Scheimpflug camera (Oculus Pentacam);
Autorefractometer (TOMEY RC-5000 and Topcon KR-1);

Secondary outcomes

1

Description

Keratometry

Timepoint

Before intervention, 30 minutes after intervention

Method of measurement

Scheimpflug camera (Oculus Pentacam);
Autorefractometer (TOMEY RC-5000 and Topcon KR-1);

2

Description

Anterior chamber parameters

Timepoint

Before intervention, 30 minutes after intervention

Method of measurement

Scheimpflug camera (Oculus Pentacam)

Intervention groups

1

Description

Intervention group: this group receives tropicamide 0.5% (one drop every 5 minutes for 2 times) drops.

Category

Treatment - Drugs

2

Description

Intervention group: this group receives tropicamide 1%

(one drop every 5 minutes for 2 times) drops.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Semnan Research and Medical Training Center

Full name of responsible person

Navid Elmi Sadr

Street address

Kowsar Semnan Research and Medical Training Center, semnan, iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz kokhaei

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Navis Elmi Sadr

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data can be shared without disclosing the identities of the participants

When the data will become available and for how long

Access period starts one year after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can use the data for systematic review studies and meta-analysis.

From where data/document is obtainable

Contact the person in charge of the scientific inquiries of the project by e-mail

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

After receiving the request e-mail, if the person is

eligible, the data will be sent
Comments