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 autorefractokeratometers. 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
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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 an 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); Autorefractokeratometer (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); Autorefractokeratometer (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
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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