

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation the effect of antiglaucoma medications on choroidal layer thickness in healthy young volunteers

Protocol summary

Study aim

Evaluation of the effect of antiglaucoma medications on choroidal thickness

Design

Healthy young volunteers randomly assigned to four groups(Timolol, Dorzolamide, Brimonidine, Latanoprost). name of each medication written on a card by a codename and the participant and operator would NOT know the real name of drug.drug instilled the right eye and placebo(artificial tear) instilled in the left eye. choroidal thickness would measure before and after 2 hours later for Timolol, Dorzolamide, Brimonidine and 12 hours later for Latanoprost by EDI-OCT Heidelberg . measurement in the center , 500 mic superior , inferior , nasal and temporal to fovea . participants , operators and data analyzer are all blinded .

Settings and conduct

Khatam Al Anbia hospital

Participants/Inclusion and exclusion criteria

Healthy young volunteers age 20-40

Intervention groups

Healthy young volunteers randomly assigned to four group topical antiglaucoma medications : Timolol, Dorzolamide, Brimonidine, Latanoprost

Main outcome variables

Choroidal layer thickness before medication and at the peak of drug effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180203038597N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Sadeq Ghafarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3846 5955

Email address

ghafarians@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Evaluation the effect of antiglaucoma medications on choroidal layer thickness in healthy young volunteers

Public title

Effect of antiglaucoma medications on choroidal thickness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy young patients

Exclusion criteria:

History of ocular disease Allergy to antiglaucoma medications Pregnancy and breastfeeding

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Volunteers choose one card randomly from the cards with written name of medication by a code. patient and operator dont know the medication name

Blinding (investigator's opinion)

Double blinded

Blinding description

Four groups of medications renamed to a codename by one of physicians. volunteers & optometrists and data analyzer would be blinded. After analysis of data the real name of drugs will defined.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University od Medical Sciences

Street address

Azadi Square , Ferdowsi University

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IRMUMS.fmREC.1395.118

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

choroidal thickness

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Choroidal thickness

Timepoint

Before medication instillation and at the peak of effect

Method of measurement

Heidelberg EDI OCT

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: right eye of volunteers randomly assigned to one of antiglaucoma drugs

Category

Treatment - Drugs

2**Description**

Control group: artificial tear instilled in the left eye of participants

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam Al Anbia hospital

Full name of responsible person

Sadeq Ghafarian

Street address

Khatam Al anbia hospital, Gharani Blvd., Mashhad

City

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9195965919

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Shoeibi Nasser

Street address
Gharani ave , Khatam Al-Anbia hospital

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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
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
Nasser Shoeibi

Position
associate 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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Person responsible for updating data

Contact

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resident

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Medical doctor

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Ophthalmology

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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

all of data would be accessible
When the data will become available and for how long
6 month after publish of results
To whom data/document is available
researchers in academic institutes
Under which criteria data/document could be used
there would no restrictions
From where data/document is obtainable
Khatam Al-Anbia Hospital - Gharani ave - Dr. ghafarian
What processes are involved for a request to access data/document
official request should send to khatam al anbia hospital
Comments