

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Assessment of efficacy of brimonidine versus latanoprost for visual improvement in normal tension glaucoma patients

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Assessment of efficacy of brimonidine versus latanoprost in normal tension glaucoma

Last update: **2021-05-20, 1400/02/30**

Update count: **0**

Design

Clinical trials with a control group, non - blindness, randomized in Permuted block method with 100 patients

Registration date

2021-05-20, 1400/02/30

Settings and conduct

The current study is a single centered Single-blinded clinical trial that will occur at Alzahra Hospital in Zahedan. Patients will be divided into two intervention groups according to randomized permuted block method. In this study patients are randomly divided into intervention groups after signing informed consent unawaresly.

Registrant information

Name

morteza Sedaghat Kia

Name of organization / entity

zaums

Country

Iran (Islamic Republic of)

Phone

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Email address

morimedico@yahoo.com

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients referring to Ophthalmology Clinic, who will be diagnosed with Normal Tension Glaucoma, based on findings such as: normal Intraocular pressure, Optic nerve changes, and visual field changes
Exclusion criteria: patients on treatment patients with drug allergy eye surgery past ophthalmologic diseases history

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group1: Prescription of eyedrop Brimonidine 0.2% made in Iranian Sina daroo inc, every 12 hours in the eye
Intervention group 2: Prescription of Eyedrop latanoprost 0.005% made in Iranian Sina daroo inc. once daily at 9 PM in the eye

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Laminar and prelaminar thickness of lamina cribrosa IOP (intraocular pressure) visual field defect

Trial completion date

empty

General information

Scientific title

Assessment of efficacy of brimonidine versus latanoprost for visual improvement in normal tension glaucoma patients

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120817010617N7**

Registration date: **2021-05-20, 1400/02/30**

Public title

Efficacy of brimonidine & latanoprost in treatment

normal tension glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referring to Alzahra Ophthalmology Clinic, Who will be diagnosed with Normal Tension Glaucoma

Exclusion criteria:

patients on treatment patients with drug allergy eye surgery past ophthalmologic diseases history

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to intervention group A and B using randomized block design with block size 6. Randomization was done using online random allocation software

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, only patients are blinded to the content of drug A or B. The examiner, optometrist and secretary of clinic are completely informed of the contents of type A and B drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr.Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-10-21, 1397/07/29

Ethics committee reference number

IR.ZAUMS.REC.1397.297

Health conditions studied

1

Description of health condition studied

Normal Tension Glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

Primary outcomes

1

Description

IOP (intraocular pressure) mmhg

Timepoint

At the beginning of the study, Then 3 months, 6 months, 9 months and 12 months after initiating medications.

Method of measurement

The Air puff tonometer Topcon

2

Description

Laminar and prelaminar thickness of lamina cribrosa using OCT of optic nerve head(ONH)

Timepoint

At the beginning of the study, Then 3 months, 6 months, 9 months and 12 months after initiating medications.

Method of measurement

laminar and prelaminar thickness of optic nerve head using cirrus OCT

3

Description

visual field defect / number of scotomas and in decibels

Timepoint

At the beginning of the study, 6 months, and 12 months after initiating medications.

Method of measurement

Humphrey field analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Prescription of eyedrop Brimonidine 0.2% made in Iranian Sina daroo inc, every 12 hours in the eye

Category

Treatment - Drugs

2**Description**

Intervention group 2: Prescription of Eyedrop latanoprost 0.005% made in Iranian Sina daroo inc. once daily at 9 PM in the eye

Category

Treatment - Drugs

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

Al-Zahra Eye hospital

Full name of responsible person

Hamid Vaezi

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Shahid Motahar Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Hamid Vaezi

Position

Ophthalmology resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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