

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of dorzolamide nanoliposomes in comparison with marketed dosage form on intraocular pressure in open angle glaucoma patients

Protocol summary

Summary

The aim of this study is evaluation of the effects of dorzolamide nanoliposomes in comparison with marketed dosage form on intraocular pressure in open angle glaucoma patients. Inclusion criteria: patients must use only one drug to reduce their intraocular pressure. Exclusion criteria: patients that have hypertension, diabetes, autoimmune disease or chronic disease. Our research is double blind, it means that both examiner and patient are blinded. the number of patients in this study is 60. primary outcome is intraocular pressure and secondary outcome is adverse effects. Eye drops in similar package will be delivered to both intervention groups. the patients are divided into two groups. Group I will be received dorzolamide nanoliposome and group II treated with dorzolamide marketed drop. One drop of the nanoliposome or marketed drop will be instilled into the eye 3 times daily for 2 months. IOP will be determined using tonometer every 2 weeks. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020426360N1**

Registration date: **2016-05-02, 1395/02/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-02, 1395/02/13

Registrant information

Name

Laleh Andishmand

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 1298

Email address

andishmand.l@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-03, 1395/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dorzolamide nanoliposomes in comparison with marketed dosage form on intraocular pressure in open angle glaucoma patients

Public title

The effects of dorzolamide nanoliposome in open angle glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients must use only one drug to reduce their intraocular pressure. Exclusion criteria: patients that have hypertension, diabetes, autoimmune disease or chronic disease.

Age

From **12 years** old to **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Vice chancellor for research of University, Ahvaz
Jundishapur University of Medical Sciences, Golestan,
Esfand street, Ahvaz

City

Ahvaz

Postal code

Approval date

2016-03-14, 1394/12/24

Ethics committee reference number

IR.ajums.rec.1394.733

Health conditions studied

1

Description of health condition studied

primary open-angle glaucoma

ICD-10 code

H40.1

ICD-10 code description

primary open-angle glaucoma

Primary outcomes

1

Description

intraocular pressure

Timepoint

before intervention, in middle(Day 14th and Day 28th)
and in long term(Day 42th and Day 56th)

Method of measurement

Goldmann applanation tonometry

Secondary outcomes

1

Description

adverse effects

Timepoint

Days 14, 28, 42 and 56

Method of measurement

patient complaint

Intervention groups

1

Description

Intervention group 1: dorzolamide nanoliposome 2%.one
drop 3 times daily for 2 months

Category

Treatment - Drugs

2

Description

Intervention group 2: Dorzolamide marketed solution
2%.one drop 3 times daily for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam khomeini Academic and Medicinal
Center

Full name of responsible person

Laleh Andishmand

Street address

Ahvaz Imam khomeini Academic and Medicinal
Center, Azadegan street, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr Nader Saki

Street address

Vice chancellor for research of Ahvaz Jundishapur
University of Medical Sciences, Ahvaz Jundishapur
University of Medical Sciences, Golestan, Esfand
street, Ahvaz

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Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Laleh Andishmand

Position

student of Pharm.D

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Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty