

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of oral saffron extract effect on intraocular pressure in pseudoexfoliation glaucoma patients

Protocol summary

Summary

pseudoexfoliation glaucoma patients whose IOP is under control with timolol and dorzolamide will be divided randomly in two 15 person groups, first group will receive oral placebo daily , second group will receive saffron capsules(30 mg) daily. intraocular pressure will be measured at first, 7th and 30th day and after one month of wash out period . If both eyes of one patient had glaucoma only one eye randomly will be entered in study. intraocular pressure values of these groups will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308298832N2**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Mohammad Hossein Jabbarpoor Bonyadi

Name of organization / entity

Gonabad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 9012

Email address

drbonyadi@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Gonabad University Of Medical Sciences

Expected recruitment start date

2013-09-09, 1392/06/18

Expected recruitment end date

2014-03-03, 1392/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral saffron extract effect on intraocular pressure in pseudoexfoliation glaucoma patients

Public title

Evaluation of oral saffron extract effect on intraocular pressure in pseudoexfoliation glaucoma patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : pseudoexfoliation glaucoma controlled with topical timolol bd and dorzolamid tds ; age >50
exclusion criteria: angle closure glaucoma; systemic compounding medication

Age

From **50 years** old to **120 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical sciences, Gadir square, Gonabad, Khorasan razavi Iran, Islamic Republic Of

City

Gonabad

Postal code

Approval date

2012-02-01, 1390/11/12

Ethics committee reference number

90/1/1

Health conditions studied

1

Description of health condition studied

pseudoexfoliation glaucoma

ICD-10 code

H40.5

ICD-10 code description

Glaucoma secondary to other eye disorders

Primary outcomes

1

Description

Intraocular pressure

Timepoint

baseline, 1st ,7th,21st and 28 day and after one month wash out

Method of measurement

Goldmann tonometry

Secondary outcomes

1

Description

Intraocular pressure

Timepoint

baseline, 1st third fourth week and after one month wash out

Method of measurement

goldmann tonometry

Intervention groups

1

Description

Placebo capsules for 30 days then 1 month wash out

Category

Treatment - Drugs

2

Description

Saffron 30 mg/daily every day for 30 days then 1 month of wash out period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Mohammad Hossein Jabbarpoor Bonyadi

Street address

Naser khosro Ave, 22 Bahman Hospital

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Hossein Jabbarpoor Bonyadi

Street address

22 Bahman Hospital Naser khosro avenue

City

Gonabad,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

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Person responsible for general inquiries

Contact

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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