Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of oral saffron extract effect on intraocular pressure in pseduexfoliation 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 , secound group will receive saffron capsules(30 mg) daily. intraocular pressure will be messured 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
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Iran (Islamic Republic of)
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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 pseduexfoliation glaucoma patients

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : pseudoexoliation glaucoma controlled with topical timolol bd and dorzolamid tds ; age >50
exclusion criteria: angle closure glaucoma; systemic componding 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, 1rst ,7th,21st and 28 day and after one month wash out
Method of measurement
Goldmann tonometry

Secondary outcomes

1

Description
Intraocular pressure
Timepoint
baseline, 1rst third fourth week and after one month wash out
Method of measurement
goldmann tonometery

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
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Naser khosro Ave, 22 Bahman Hospital
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Sponsors / Funding sources

1

Sponsor
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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
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

Person responsible for general inquiries

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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