Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The Efficacy of Supplemental Saffron in Patients with Age-Related Macular Degeneration

Protocol summary

Summary

The aim of this double blind clinical trial is to assess the electroretinography(ERG) changes in patients with age-related macular degeneration (AMD) after supplemental saffron consumption. This trial will be conducted in Farabi hospital and a total number of 80 eyes will be studied. Patients suffering from AMD will be recruited and then ERG, fluorescein angiography (FA), and ocular coherence tomography (OCT) will be performed for each patient. Based on FA interpretations, patients will be divided into two groups: wet (neovascular) or dry (non-neovascular). Dry subtype patients will be randomized to the saffron or the control group by a third person who is completely blind to the patients' information. Dry subtype patients will receive two capsules (saffron or placebo) per day for six months and will undergo ERG and OCT by months 3 and 6. Wet subtype patients will be randomized to the saffron or the control group in the same manner and will receive the same medications. Each saffron capsule contains 15mg of hydro-alcoholic saffron. Placebo capsules are identical in appearance to saffron and are dispensed by the investigational drug pharmacist. Intravitreal bevacizumab (IVB) will be injected for wet subtype patients monthly for three times. Inclusion criteria: visual acuity: 20/40 >⋯ > 20/400; no prior treatment for AMD definite diagnosis. Exclusion criteria: any concurrent ocular disease (e.g. diabetic retinopathy, retinal vascular disease); history of keratoconus history of glaucoma. Changes by months 3 and 6 will be compared to the baseline and the efficacy of this treatment will be analyzed by statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205219820N1**
Registration date: **2012-09-30, 1391/07/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-09-30, 1391/07/09

Registrant information

Name
Alireza Lashay
Name of organization / entity
Eye research center
Country
Iran (Islamic Republic of)
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+98 21 5512 1002
Email address
lashay@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Eye Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Supplemental Saffron in Patients with Age-Related Macular Degeneration

Public title

The Efficacy of Supplemental Saffron in Patients with Age-Related Macular Degeneration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: visual acuity: 20/40 >⋯ > 20/400; being available; no prior treatment for AMD; definite diagnosis; being between the study range of age.
Exclusion criteria: any concurrent ocular disease (e.g. diabetic retinopathy, retinal vascular disease); history of keratoconus; history of glaucoma.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Tehran University of Medical Sciences

Street address

Enghelab Square

City

Tehran

Postal code

Approval date

2011-06-20, 1390/03/30

Ethics committee reference number

3216/210/90/ص

Health conditions studied

1

Description of health condition studied

Age-related macular degeneration

ICD-10 code

H35.3

ICD-10 code description

Degeneration of macula and posterior pole

Primary outcomes

1

Description

ERG

Timepoint

START STUDY.3MONTH.6MONTH

Method of measurement

Amplitude and implicite time

2

Description

OCT

Timepoint

at the beginning, month 3 and month 6

Method of measurement

Thickness

Secondary outcomes

1

Description

OCT

Timepoint

3 month

Method of measurement

thickness

Intervention groups

1

Description

saffron capsule 15mg, bid, for 6 month

Category

Treatment - Drugs

2

Description

placebo tablet, bid, for 6 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Dr. Sadough

Street address

Farabi Eye Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Eye Research center
Full name of responsible person
Dr. Iashay
Street address
Qazvin Square, Farabi Eye Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Eye Research center
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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Person responsible for updating data

Contact

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