

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)

Phone

+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 implicate 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. lashay

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

Farabi Eye Hospital

Full name of responsible person

Dr. Gholamreza Sadough

Position

resident

Other areas of specialty/work

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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