Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Comparing the synergistic effect of Combination of curcumin and piperine supplementation as an adjuvant treatment to the usual treatment method using Bevacizumab in patients with neovascular age-related macular degeneration

Protocol summary

Study aim

A comparative study of the synergistic effect of the combination of curcumin and piperine as an adjuvant treatment and bevacizumab injection as a common treatment in patients with age-related macular degeneration of the neovascular type.

Design

After approving the plan and obtaining necessary permits, 60 patients were selected and randomly divided into two groups, case and control. Randomization is one of the important principles in the design and implementation of this plan. By using this method, the possibility of disturbance in the variable factors affecting the test results is reduced and better confidence is obtained in the interpretation of the results. In this clinical trial design with 30 control and 30 intervention people, the randomization method is used to randomly distribute people into two different groups. After selecting the subjects, the researcher first explained the objectives of the study to them in a simple and understandable language, and then provided them with an informed consent form to sign after careful study.

Settings and conduct

This plan will be carried out in Al-Zahra Ophthalmology Hospital under Zahedan University of Medical Sciences. In such a way that the case group will be given real capsules and the control group will be given placebo capsules.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Signed written informed consent • Aged 45 - 80 years, male or female • Diagnosed with neovascular AMD and with active lesions. Exclusion Criteria: • Any history of allergy or sensitivity to turmeric, pepper, curcumin or piperine • Any history of allergy or sensitivity to antiVGEFs •

Intervention groups

The intervention groups will be given a combination of curcumin and peprine along with the common drug bevacizumab

Main outcome variables

Macular thickness; macular fluid; density of vessel in OCTA; Best Corrected Visual Aquity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230614058480N1**
Registration date: **2023-09-19, 1402/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-19, 1402/06/28**
Update count: **0**

Registration date

2023-09-19, 1402/06/28

Registrant information

Name

Alireza Maleki

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the synergistic effect of Combination of curcumin and piperine supplementation as an adjuvant treatment to the usual treatment method using Bevacizumab in patients with neovascular age-related macular degeneration

Public title

Synergistic effect of Combination of curcumin and piperine supplementation as an adjuvant treatment to the usual treatment method using Bevacizumab in patients with neovascular age-related macular degeneration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signed written informed consent Age 45 - 80 years, male or female Neovascular AMD is diagnosed with active lesions

Exclusion criteria:

Any history of allergy or sensitivity to turmeric, pepper, curcumin or piperine Any history of allergy or sensitivity to antiVGEFs With vitreous hemorrhage in the studied eyes With geographic atrophy, epiretinal membrane or hard subfoveal exudates involving the foveal in the studied eyes With opacification of the refractive medium (such as apparent cataract) or pupillary constriction that significantly interferes with vision testing or evaluation of the anterior segment and fundus in the study eyes. With rhegmatogenous retinal detachment, macular hole, or choroidal neovascularization (CNV) of any cause other than AMD (eg, fundus angioid streaks, ocular histoplasmosis, pathologic myopia, trauma) in study eyes. With apparent afferent pupillary defect (RAPD) in the studied eyes With polypoidal choroidal vasculopathy (PCV) or retinal angiomatous proliferation (PAP) in the studied eyes With intraocular pressure above 25 mmHg despite treatment With active inflammation in each eye, such as conjunctivitis, keratitis, scleritis, blepharitis, endophthalmitis, and uveitis. The study eye received topical or retinal photocoagulation more than twice or within 3 months before screening. The study eye received the following intraocular surgery or laser therapy in the macula (eg, macular displacement surgery, glaucoma filter surgery, transpupillary thermotherapy, macular photocoagulation, vitreous incision surgery, optic nerve dissection, optic nerve sheath membrane dissection). However, patients who received vertporfin photodynamic therapy, cataract surgery, or YAG posterior capsular dissection more than 3 months prior to screening will not be excluded. Any eye received antiangiogenic drugs in the 2 months before screening or patients who received systemic antiangiogenic drugs in the 3 months before screening (eg, pegaptanib, aflibercept, ranibizumab, bevacizumab, or canbercept). Any eye had received an intraocular injection of a corticosteroid (eg, triamcinolone acetonide) within 3 months prior to screening, or had received an ophthalmic injection of a corticosteroid within 1 month prior to screening for systemic disease, treatment, or other conditions. With a history of sensitivity to sodium fluorescein and indocyanine green PLT≤100×109/L, BUN or Cr>1.5×ULN (upper limit of normal), TT (thrombin time) or PT (prothrombin time) >1.0×ULN (upper limit of normal), take antiplatelet. Medications or anticoagulants 1 month before screening With surgery one month before screening, or with a current unhealed wound, ulcer, or fracture Diabetic patients without glucose control or with diabetic retinopathy With a history of myocardial infarction in the 6 months before screening With intravascular coagulation activity and significant bleeding tendency before screening Systemic autoimmune disease Any uncontrolled disease (such as severe systemic mental, neurological, cardiovascular, respiratory, and malignancies) Pregnant and lactating women or patients who cannot take contraceptive measures Poor compliance Patients who participated in or were currently participating in other clinical trials within 30 days prior to screening. Patients deemed unsuitable for enrollment by the investigator

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, we use a table of random numbers and place each client in the intervention or control group. One of the advantages of this type of randomization is that the type of treatment assigned to the two groups is completely unpredictable

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Zahedan University of Medical Sciences

Street address
Mottahari blvd.

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Zahedan

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Sistan-va-Balouchestan

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9816743463

Approval date
2023-07-08, 1402/04/17

Ethics committee reference number
IR.ZAUMS.REC.1402.138

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
Central Sub-Field Retinal Thickness (CSFT)

Timepoint
0,1 month, 2 and 3 months after intervention

Method of measurement
Objective measurement of macular thickness (from OCT findings)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with neovascular AMD and diagnosed with active lesions. Capsules containing curcumin 1000mg with 10mg of piperine will be provided by Biotechnology Research Center, Mashhad University of Medical Sciences. Standard Treatment intervention groups will receive standard treatment of monthly 1.25 mg of intravitreal Bevacizumab Duration of intervention 3 months

Category
Treatment - Drugs

2

Description
Control group: patients with neovascular AMD and diagnosed with active lesions.placebo Capsules will be provided by Biotechnology Research Center, Mashhad University of Medical Sciences.Standard Treatment intervention groups will receive standard treatment of monthly 1.25 mg of intravitreal Bevacizumab Duration of intervention3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Eye Hospital of Zahedan

Full name of responsible person
Alireza Maleki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
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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

Zahedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Alireza Maleki

Position
Assistant Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable