

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Determination of the effect of Gingko Biloba extract on redox state of human serum and aqueous albumin in patients with senile cataract

Protocol summary

Study aim

Determination of The effect of Gingko Biloba extract on redox state of human serum and aqueous albumin in patients with senile cataract

Design

Community based, parallel-group, double-blinded, randomised controlled trial

Settings and conduct

200mg GbE supplement capsules and identical placebo was prescribed to the patients for 6 months post-cataract surgery, patients and their study-groups were coded and followed up using slit-lamp examination at 6,12 and 36 months post-op and their Fibrotic and Pearl Posterior Capsule Opacification was surveyed and graded. Data analyses were conducted using the coded data, so the patients, care-giver and data analyst were all blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: senile cataract Exclusion criteria: a history of cardiac, renal, neurologic, hematologic, DM, thyroidal and rheumatologic diseases, Receiving of estrogen-steroid, immunosuppressive and anticoagulant-anti platelet agents, History of ophthalmic diseases and surgery such as uveitis, retinitis pigmentosa and trabeculectomy

Intervention groups

GBE, capsule 200 mg PO, daily for 16weeks

Main outcome variables

Fibrotic Posterior Capsule Opacification Pearl Posterior Capsule Opacification

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190912044755N1**

Registration date: **2019-10-10, 1398/07/18**

Registration timing: **retrospective**

Last update: **2019-10-10, 1398/07/18**

Update count: **0**

Registration date

2019-10-10, 1398/07/18

Registrant information

Name

Ahmad Ahmadzadeh Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 5734

Email address

ahmadzdh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-02-19, 1393/11/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

2015-02-19, 1393/11/30

Actual recruitment end date

2018-10-22, 1397/07/30

Trial completion date

2019-04-19, 1398/01/30

Scientific title

Determination of the effect of Gingko Biloba extract on redox state of human serum and aqueous albumin in patients with senile cataract

Public title

Survey of the effect of Gingko Biloba on cataract

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Senile cataract

Exclusion criteria:

History of cardiac diseases History of renal diseases
History of neurological diseases History of Diabetes
Mellitus History of rheumatologic diseases History of
hematologic diseases History of thyroid diseases
Receiving of estrogen-steroid, immunosuppressive and
anticoagulant-anti platelet agents History of ophthalmic
diseases and surgery

Age

From **50 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **146**

More than 1 sample in each individual

Number of samples in each individual: **2**

1 or 2 eyes in each patient

Actual sample size reached: **134**

More than 1 sample in each individual

Actual sample size in each individual: **2**

1 or 2 eyes in each patient

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization on an individual level using 4 number
blocks created in excel software. Allocation concealment
has been carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

A placebo identical to the GbE capsules was provided to
the patients, so neither the patient nor the physician
were aware of the supplementation. Patients and their
data were coded and documented using codes and data
analysis was carried out using these codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical
Sciences

Street address

17th km Khazarabad Blv

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2011-12-21, 1390/09/30

Ethics committee reference number

90-114

Health conditions studied

1

Description of health condition studied

Senile cataract

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Posterior Capsule Opacification

Timepoint

6, 12, 36 weeks after cataract surgery

Method of measurement

Slit-lamp bio microscopic examination of eyes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: GBE,capsule 200 mg po,daily for
16weeks

Category

Prevention

2

Description

Control group: placebo,capsule 200 mg po,daily for
16weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Boali sina hospital of sari

Full name of responsible person

Ahmad Ahmadzadeh Amiri

Street address

Pasdarán Blv

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Postal code

4815838477

Phone

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Email

ahmadzdh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Deputy of research and technology of Mazandaran
University of Medical Sciences

Street address

17 Km of Khazar abad Blv

City

Sari

Province

Mazandaran

Postal code

919748471

Phone

+98 11 3354 3081

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ahmadzdh@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ahmadzadeh Amiri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Vitreoretinal fellowship

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ahmad Ahmadzadeh Amiri

Position

Assistant Professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

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