

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Saffron extract in the treatment of mild to moderate Alzheimer's disease: A double blind randomized controlled trial.

Protocol summary

Summary

The objective of this study was to assess the efficacy and safety of Capsule of Crocus sativus, in patients with mild to moderate Alzheimer's disease, over the 20 weeks. This study will be undertaken in 3 centers in Tehran, Iran. Patients with mild to moderate Alzheimer's disease aged between 65-80 years with a score of ≥ 12 on the cognitive subscale of Alzheimer's Disease Assessment Scale (ADAS-cog) and ≤ 2 on the Clinical Dementia Rating (CDR) will be randomized to Donepezil (10 mg/day) or Capsule of Crocus Sativus (30 mg/day). The main efficacy measures will be the change in the ADAS-cog and CDR-SB scores compared to baseline. In addition, side effects will be systematically recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711051556N1**

Registration date: **2009-02-12, 1387/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-02-12, 1387/11/24

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2006-11-10, 1385/08/19

Expected recruitment end date

2009-04-10, 1388/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron extract in the treatment of mild to moderate Alzheimer's disease: A double blind randomized controlled trial.

Public title

Saffron and Alzheimer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: A diagnosis of probable Alzheimer's disease according to the criteria of National Institute of Neurological and Communicative Disorders and Stroke and Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA); Presence of mild to moderate dementia [score of ≥ 12 on the cognitive subscale of Alzheimer's Disease Assessment Scale (ADAS-cog) and ≤ 2 on Clinical Dementia Rating Scale (CDR)]. Exclusion Criteria: Concomitant diseases such as hypertension, congestive heart failure, non-insulin dependent diabetes mellitus and hypothyroidism; Patients with evidence of other neurodegenerative disorders; Any cardiovascular disease likely to prevent

completion of the study; Clinically significant psychiatric diseases; Urinary outflow obstruction; Active peptic ulcer; Any history of epilepsy; Significant drug or alcohol misuse; Drugs with anticholinergic effects or cholinomimetic effects.

Age

From **65 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not 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

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Postal code

Approval date

2005-12-01, 1384/09/10

Ethics committee reference number

4843

Health conditions studied

1

Description of health condition studied

Mild to moderate Alzheimer

ICD-10 code

F00

ICD-10 code description

Dementia in Alzheimer's disease

Primary outcomes

1

Description

Severity of Alzheimer

Timepoint

Every month

Method of measurement

ADAS-cog

Secondary outcomes

1

Description

Severity of Alzheimer

Timepoint

Every Month

Method of measurement

CDR-SB

Intervention groups

1

Description

Intervention: Capsule of Saffron 30 mg/day

Category

Treatment - Drugs

2

Description

Control: Tab Donepezil 10 mg/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Ward, Imam Khomeini Hospital, Tehran

Full name of responsible person

Dr. Mehdi Shafiee

Street address

City

2

Recruitment center

Name of recruitment center

Neurology ward, sina Hospital, Tehran

Full name of responsible person

Dr. Mansoureh Togha

Street address

City

3

Recruitment center

Name of recruitment center

Dept Of neurology, Qom University of Medical sciences

Full name of responsible person

Dr. hejazi

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Grant name

Grant code / Reference number

4843

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

PhD., FBPharmacolS. Prof. of Clinical

Psychopharmacology

Other areas of specialty/work

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Web page address

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