Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Crocus sativus stigma ethanolic extract on cognitive criteria, anti-inflammatory and antioxidant markers in Nesyan patients (Alzheimer's disease)

Protocol summary

Study aim

The aim of this study is to investigate the effect of saffron extract on cognitive factors and also anti-inflammatory and antioxidant measures in alzheimer disease.

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 60 patients

Settings and conduct

Patients over 65 who referring to a neurologist with forgetfulness.Diagnosis of dementia(alzheimer type) is based on clinical and paraclinical criteria. The interviewer,participant and analyst are unaware of the contents of the packets.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1- Patients older than 65 years (Late Onser Alzheimer Disease) 2.Dementia diagnosis according to DSM5 score between 11 and 24 Exclusion criteria 1.Reversible dementia including delirium, drug causes, endocrine causes(hypothyroidism), metabolic causes, electrolyte,space occupying lesion, infections 2-irreversible cortical causes including frontotemporal dementia and lewy body 3.Irreversible subcortical causes including degenerative causes (such as corticobasal ganglia),inflammation (such as lupus, vasculitis, and MS). 4.changes in anti-inflammatory criteria: Fever,infections,vasculitis,antioxidants,anti-inflammatory drugs such as corticosteroids (asthma, rheumatoid arthritis, etc.) 5.Patients with other psychologic or other neurologic disease based on DSM5 criteria 6. People with MMSE scores above 24 and below 11

Intervention groups

Patients are divided into two groups of intervention and control group. All participants receive Alzheimer's medication from Anticholinesterase group. The control group will receive saffron capsules of 15 mg twice daily and the control group will receive similar capsules of placebo (containing starch).

Main outcome variables

MMSE; TNF-alpha; IL-6; IL-1 beta; MDA (malonaldehyde); TAC (total antioxidant capsity); SOD (Superoxide dismutant); GPX (glutathione peroxidase)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190428043409N1**
Registration date: **2019-09-21, 1398/06/30**
Registration timing: **prospective**

Last update: **2019-09-21, 1398/06/30**
Update count: **0**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

Leila Rasi marzabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9528

Email address

leili_rasi_m@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Crocus sativus stigma ethanolic extract on cognitive criteria, anti-inflammatory and antioxidant markers in Nesyan patients (Alzheimer's disease)

Public title
effect of saffron on dementia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1) Man and woman Patients older than 65 years (Late Onser Alzheimer Disease) Diagnosis of dementia based on DSM5 criteria and diagnosis of neurologist (confirmation with brain MRI and blood tests to exclude other causes) 3. Mild to moderate Alzheimer disease based on the MMSE cognitive test score between 11 and 24
Exclusion criteria:
Reversible dementias include delirium, pharmacotic agents, endocrine causes (hypothyroidism), metabolic causes, electrolyte, SOL, infections (encephalitis, syphilis, and AIDS) and atherosclerosis. irreversible cortical causes including fronto-temporal and lewy body dementia. irreversible subcortical causes include degenerative causes (such as corticobasal ganglia), inflammatory causes (such as lupus, vasculitis and multiple sclerosis) The cases that change the anti-inflammatory criteria of a person, such as fever, acute infectious diseases, vasculitis, antioxidant medications, anti-inflammatory drugs such as corticosteroids (such as asthma, rheumatoid arthritis, etc.) Patients with any other psychological or neurological disease based on DSM5 criteria. People with MMSE score higher than 24 (MCI) and below 11 (severe dementia) do not enter the study.
Age
From **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
One blood sample at the beginning of the intervention and one at the end of the study

Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be coded and randomly assigned random numbers in the placebo or saffron group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Capsules can be placed in plastic cans in the form of placebo boxes and coded to blinding both (clinical caregiver) and drug receptor (participant). To evaluator blinding, the questionnaires will be without a name and with reference codes. To control blindness, the saffron and control group (drug or placebo) will not be mentioned.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee for Biomedical Research
Street address
82No, Ghaem alley,Karpishe street, Dr.gharib Street,Azadi Street
City
Tabriz
Province
East Azarbaijan
Postal code
5173853467
Approval date
2019-07-15, 1398/04/24
Ethics committee reference number
IR.TBZMED.REC.1398.438

Health conditions studied

1

Description of health condition studied
Dementia - alzheimer
ICD-10 code
G30.1
ICD-10 code description
Alzheimer's disease with late onset

Primary outcomes

1

Description

Memory scores in the mini mental state exam(MMSE) questionnaire

Timepoint

MMSE measurements at the beginning of the study (before the intervention) and 16 weeks after the intervention

Method of measurement

mini mental state exam

2

Description

Tumor necrosis factor alpha

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

laboratory kits

3

Description

Interleukin 6

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

Laboratory kits

4

Description

Interleukin 1 beta

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

Laboratory kits

5

Description

Glutathione peroxidase

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

Laboratory kits

6

Description

superoxid dismutase

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

Laboratory kit

7

Description

Total Antioxidan Capacity

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

Laboratory kit

8

Description

Serum levels of malondialdehyde

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

laboratory kits

Secondary outcomes

1

Description

Memory level

Timepoint

The beginning of the study (before the intervention) and 16 weeks after the start of the intervention

Method of measurement

MMSE questionnaire

Intervention groups

1

Description

Intervention group: Giving the extract (capsule) of saffron 15mg of the company's "green herbal products", twice a day

Category

Treatment - Drugs

2

Description

Control group: Starch containing capsules twice a day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Talebi

Street address

Tabriz Neuroscience Research Center,Imam Reza Hospital, End of Golgasht St, Azadi St. -

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5166614756

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mahnaz Talebi

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Leila Rasi marzabadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data on the main outcome is shared
When the data will become available and for how long
Information will be available 6 months after the publication of the paper
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Information will be available for further research and similar studies. The publication of articles using the results of this research will only be allowed by researchers. If more papers are published using the data in this study, the intellectual property rights of the researchers should be considered.
From where data/document is obtainable
leila rasi marzabadi email.address: leili_rasi_m@yahoo.com
What processes are involved for a request to access data/document
If the request does not include unusual items, the information will be provided to them at least 10 working days after the approval of the Research Director of the Neuroscience Research Center.
Comments