

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of *Crocus sativus stigma* ethanolic extract on cognitive criteria, anti-inflammatory and antioxidant markers in Nesyhan 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 Onset 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 capacity); 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 Onset 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, pharmacologic 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 analyst

**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 Gologasht St, Azadi St. -

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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**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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university

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## Person responsible for scientific inquiries

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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**