

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effectiveness of the adjuvant treatment with a compound of sedge plant, saffron and honey to conventional treatment for improvement of cognitive performance of patients with dementia

Protocol summary

Summary

This is a double-blinded clinical trial study, which assessment person and drug delivery person were not aware about drug and placebo and the patients were not aware about the groups. The patients were selected from geriatric clinic (60 patients), and divided randomly into intervention group (30 patients) and control group (30 patients). Inclusion criteria: Upper 50 years old; slight to moderate dementia; according DSM-IV criteria; acceptance to enter this project; under drug therapy. Exclusion criteria: Mental retardation depend on DSM-IV criteria; Side effect that patients couldn't continue these herbal drugs such as gastrointestinal side effect; other psychiatrist disorder; using other herbal medicine, or using other traditional treatment such as homeopathy. For intervention group, daily consumption 50 mg sedge and 30 mg saffron and honey for 3 months was prescribed. And for control group same dosage placebo was prescribed. Adenborok scale for cognitive assessment and GDS for depression assessment, before intervention, the first month of intervention and the second months of the intervention was used.

General information

Acronym

ADT

IRCT registration information

IRCT registration number: **IRCT2016101030255N1**

Registration date: **2017-01-20, 1395/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

Victoria Omranifard

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of the adjuvant treatment with a compound of sedge plant, saffron and honey to conventional treatment for improvement of cognitive performance of patients with dementia

Public title

The Effectiveness of the adjuvant treatment with a compound of sedge plant, saffron and honey to conventional treatment for improvement of cognitive performance of patients with dementia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Upper 50 years old; 2-slight to moderate dementia according DSM-IV criteria; 3-acceptance to enter this project; 4-under drug therapy. Exclusion criteria: 1-Mental retardation according DSM-IV criteria; 2-Side effect that patients couldn't continue these herbal drugs such as gastrointestinal side effect; 3-other psychiatrist disorder; 4-using other herbal medicine, or using other traditional treatment such as homeopathy.

Age

From **49 years** old to **100 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jerib Street, Davazeh Shiraz, Isfahan

City

Isfahan

Postal code

Approval date

2016-04-03, 1395/01/15

Ethics committee reference number

IR.MUI.REC.1395.3.043

Health conditions studied

1

Description of health condition studied

Dementia in Alzheimer disease with late onset

ICD-10 code

G30.1

ICD-10 code description

Dementia in Alzheimer disease with late onset

Primary outcomes

1

Description

cognitive function

Timepoint

before treatment-first month and second month of treatment

Method of measurement

Adenbrok scale

Secondary outcomes

1

Description

depression

Timepoint

before-first month and second month of treatment

Method of measurement

Global depression scale

Intervention groups

1

Description

During the 3 months , 50 mg sedge and 30 mg honey with saffron for treatment group.

Category

Treatment - Drugs

2

Description

During the 3 months , 50 mg starch instead of sedge and 30 mg candy juice instead of honey with saffron for control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

geriatric clinic, Noor Hospital

Full name of responsible person

Asiyeh Almasi

Street address

Geriatric Clinic, Mohtasham Kashani street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar jerib Street, Darvazeh shiraz, Isfahan

City

Isfahan

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan 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**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Asiyeh Almasi

Position

Master degree of psychology

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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