Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of Vaj (Acorus calamus) syrup on mild to moderate Alzheimer's disease in patients referring to the neurology clinic

Protocol summary

Summary

This randomized, controlled clinical trial, was conducted to investigate the effect of the Iranian medicine called Vaj syrup (Acorus calamus) on the severity of mild to moderate Alzheimer's disease. Patients should be 50 to 80 years old and have a CDR score of less than or equal to 2 and an ADAS-COG score of 12 or higher to participate in the study. Exit criteria include chronic physical or psychosocial disorders other than Alzheimer's, and side effects of the drug. This study is performed on Alzheimer's patients referred to the Neurological Specialty Clinic whose diagnosis is definite by the neurologist, and the minimum sample size is 20 people. In this study, the intervention group, half an hour before each meal received the Vaj syrup. each time they received 10 mg with the common drug, and the control group received only the common medicine. The severity of Alzheimer's disease at baseline 4, 8 and 12 weeks after the intervention is measured using standard CDR and ADAS-COG questionnaires.Therefore, considering the effectiveness of this plant in improving memory and strengthening the brain in new articles and prescribing it in Iranian literature for years to strengthen memory and that there has not yet been any research on its efficacy in humans, it was decided that investigate the effect of Vaj syrup on a patient with Alzheimer's in a Clinical Trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102030776N2**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name
Mohadese Kamali
Name of organization / entity
Kerman University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Traditional Medicine and History Research Center of Shiraz University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Vaj (Acorus calamus) syrup on mild to moderate Alzheimer's disease in patients referring to the neurology clinic

Public title

The effect of a Vaj (Acorus calamus) syrup on Alzheimer's

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged over 50 years؛ CDR score less

than or equal to 2؛ ADAS-COG score greater than or equal to 12؛ no heart disease؛ no high blood pressure؛ no drug abuse and alcohol dependency؛Non use of anticoagulants؛ no diabetes -ability to participate in the study؛ no more than 80 years old؛ definite Alzheimer's disease Outcome criteria : bipolar disorder ؛ mild to severe depression ؛ co-morbidity with other neurological diseases ؛ inability to participate in the study؛ Inability to continue treatment ؛ causing side effects

Age
From **46 years** old to **16 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Faculty of Medicine, Traditional Medicine Research Center and Medical History, Zand Avenue, Shiraz, Iran

City
Shiraz

Postal code
7134845794

Approval date
2016-12-10, 1395/09/20

Ethics committee reference number
IR.SUMS.REC.1395.82

Health conditions studied

1

Description of health condition studied
Alzheimer

ICD-10 code
G32

ICD-10 code description
Other degenerative disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description
Severity of Alzheimer

Timepoint
four, eight, twelve weeks after intervention

Method of measurement
CDR and ADAS-COG questionnaire

Secondary outcomes

1

Description
side effects

Timepoint
four, eight, twelve weeks after intervention

Method of measurement
Self-made questionnaire

Intervention groups

1

Description
The control group is only used common drug (galantamine pill, rivastigmine capsule or danepzil tablet) for 12 weeks.

Category
Treatment - Drugs

2

Description
Intervention group was received Vaj syrup half an hour before each meal, each time they received 10 mg with the common medicine.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat clinic 4

Full name of responsible person
Mohadese Kamali

Street address
The end of Shahid rajaee street, Kerman

City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Traditional Medicine and History Research Center of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mahdi Pasalar
Street address
Faculty of Medicine, Traditional Medicine Research Center and Medical History, Zand Avenue, Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Traditional Medicine and History Research Center of Shiraz 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

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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*