

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The Investigation on the Effect of Boswellia resin Extract on Plasma Levels of inflammatory factors in Patients with Alzheimer's disease

Protocol summary

Study aim

Investigation of anti-inflammatory effect of Boswellia resin extract on inflammatory factors in Alzheimer's patients

Design

Two arm parallel groups randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Trial will be performed in Imam Hossein hospital based on block randomization in double blind manner. Every person who is involved in caring and treatment of patients including proxies, physicians and nurses are masked and investigators are all masked also

Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive DSM-IV Positive NINCDS/ADRDA MMSE includes 10-26 No family history of Alzheimer's disease Hamilton test equal or less than 12 in 17th item Memory score below 1 BM includes 18-25 No background of peptic ulcer, surgery of digesting system, or haemorrhage of digesting system No taking NSAIDs drug compounds or systemic corticosteroid during two months, and continuously before research No alcohol consumption age range is 55-85 Exclusion criteria: Turning to negative DSM-IV during Boswellia resin extract period Turning to positive NINCDS/ADRDA during Boswellia resin extract period Acute viral, bacterial or severe infectious disease during research

Intervention groups

Boswellia resin extract receiving group, Placebo group

Main outcome variables

Plasma inflammatory factors, MMSE score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033086N3**

Registration date: **2019-04-08, 1398/01/19**

Registration timing: **retrospective**

Last update: **2019-04-08, 1398/01/19**

Update count: **0**

Registration date

2019-04-08, 1398/01/19

Registrant information

Name

Saeed Karima

Name of organization / entity

Shahid Beheshti University of Medical Sciences (SBMU)

Country

Iran (Islamic Republic of)

Phone

+98 21 9666 1028

Email address

karima@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-23, 1396/03/02

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

2017-07-05, 1396/04/14

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2019-02-21, 1397/12/02

Scientific title

The Investigation on the Effect of Boswellia resin Extract on Plasma Levels of inflammatory factors in Patients with Alzheimer's disease

Public title

The Investigation on the Effect of Boswellia resin Extract on Plasma Levels of inflammatory factors in Patients with Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive DSM-IV Positive NINCDS/ ADRDA MMSE includes 10-26 No family history of Alzheimer's disease Hamilton test is less than or equal to 12 in 17th item Memory score below 1 BMI includes 18-25 No background of peptic ulcer, surgery of digesting system, or haemorrhage of digesting system No taking NSAIDs or systemic corticosteroid during previous two months No alcohol consumption Age range is 55-85

Exclusion criteria:

Turning to negative DSM-IV during Boswellia resin extract period Turning to positive NINCDS/ ADRDA during Boswellia resin extract period Acute viral, bacterial or severe infectious disease during research

Age

From **55 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was designed based on four-sized block randomization. A non-ordering computer sequence list was generated by an epidemiologist. Codes were written on envelopes and medication bottles. Patients allocation and sequencing were done blind. Following patients assessment by doctor, according to the admission sequence, the envelopes with the same number will be opened. Then according to the bottle code which is written in envelope, bottle will be given to patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients allocation and sequencing are done blind. All staffs who were involved to perform the enrollment, physicians, nurses and investigator team are all masked. Therefore, nobody knows the intervention is Boswellic resin extract or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid beheshti University of Medical Sciences, School of Medicine

Street address

Ground floor, medical faculty, Koodakyar Alley, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2016-11-15, 1395/08/25

Ethics committee reference number

IR.SBMU.MSP.REC.1395.608

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Pro- and anti-inflammatory factors

Timepoint

At the recruitment day and after intervention period

Method of measurement

ELISA assay kit

2

Description

MMSE (Mini-Mental State Examination) test

Timepoint

At the recruitment day and after intervention period

Method of measurement

MMSE questionnaire (contained 30 question point involved evaluation of attention and calculation, recall, ability to follow simple commands and orientation)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Boswellia Resin extract receiving group, 3 times/day (400 mg)

Category

Treatment - Drugs

2

Description

Control group: Placebo group, 3 times/day (400 mg)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Behnam Safarpour Lima

Street address

Shahid Madani St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1617948615

Phone

+98 21 7343 3000

Email

info@ehmc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behnam Safarpour Lima

Street address

Shahid Madani St., Tehran, Iran

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Province

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Postal code

1617948615

Phone

+98 21 7343 3000

Email

info@ehmc.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behnam Safarpour Lima

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Medical doctor

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Person responsible for updating data

Contact

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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

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

collected deidentified IPD, IPD collected for the primary outcome measure only

When the data will become available and for how long

Deidentified data will be available starting from April, 2021

To whom data/document is available

People working in academic institutions or people working in businesses.

Under which criteria data/document could be used

No specific condition

From where data/document is obtainable

Behnam Safarpour Lima, Shahid Madani St., Tehran, Iran, Tel: +982173433000 Mob. 091229811576

What processes are involved for a request to access data/document

The process is: 1- Asking a written request contain the main reasons of data importance for the applicant 2- After receiving the request letter, data will be provided in two weeks.

Comments