

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Efficacy of inflawell capsules containing Boswellic acids on behavioral and cognitive symptoms and DTI changes in patients with frontotemporal dementia

Protocol summary

Study aim

Efficacy of inflawell capsules containing Boswellic acids on behavioral and cognitive symptoms and DTI changes in patients with frontotemporal dementia

Design

Single center Clinical trial with a single assignment group, phase 2 on 20 patients

Settings and conduct

Trial will be performed in Roozbeh hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: behavioral and language variant of Frontotemporal dementia based on guidelines: Rascovsky K, Hodges JR, Knopman D, et al. Sensitivity of revised diagnostic criteria for the behavioural variant of frontotemporal dementia. Brain. 2011;134; Gorno-Tempini ML, Hillis AE, Weintraub S, et al. Classification of primary progressive aphasia and its variants. Neurology. 2011;76:1006-1014. Exclusion criteria: other specific diseases of the central nervous system such as Parkinson's, multifactorial dementia, anterior brain dementia, Huntington's disease, hydrocephalus, brain tumors confirmed by MRI, severe paralysis of the nerve of the supernuclear body, epilepsy, clots between layers of brain tissue, multiple sclerosis and other dementias; taking NSAIDs and systemic corticosteroids for previous two months continuously; severe cardiovascular disease, kidney and liver disorders; psychiatric disorders include bipolar disorder and schizophrenia under medication; drugs or alcohol abuse; brain-related surgical interventions; head trauma and progressive degenerative motor disorder; metabolic and systemic diseases.

Intervention groups

Inflawell receiving group, 3 month, 3 times/day, Oral Administration (400 mg), Inflawell capsules containing Boswellic acids has been provided by KondorPharma company (Canada) in orange gelatin capsules (400 mg /

capsule) and were packed in brown containers.

Main outcome variables

Cognitive and behavioral symptom changes; DTI (Diffusion tensor imaging) MRI changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033086N8**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

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

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of inflawell capsules containing Boswellic acids on behavioral and cognitive symptoms and DTI changes in patients with frontotemporal dementia

Public title
Efficacy of inflawell capsules on behavioral and cognitive symptoms and DTI changes in patients with frontotemporal dementia

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Behavioral variant of Frontotemporal dementia based on guideline: Rascovsky K, Hodges JR, Knopman D, et al. Sensitivity of revised diagnostic criteria for the behavioural variant of frontotemporal dementia. Brain. 2011;134 Language variant of Frontotemporal dementia based on guideline: Gorno-Tempini ML, Hillis AE, Weintraub S, et al. Classification of primary progressive aphasia and its variants. Neurology. 2011;76:1006-1014
Exclusion criteria:
 Other specific diseases of the central nervous system such as Parkinson's, multifactorial dementia, anterior brain dementia, Huntington's disease, hydrocephalus, brain tumors confirmed by MRI, severe paralysis of the nerve of the supranuclear body, epilepsy, clots between layers of brain tissue, multiple sclerosis and other dementias Taking NSAIDs and systemic corticosteroids for previous two months continuously Severe cardiovascular disease, kidney and liver disorders Psychiatric disorders include bipolar disorder and schizophrenia under medication Drugs or alcohol abuse Brain-related surgical interventions head trauma and progressive degenerative motor disorder Metabolic and systemic diseases

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 20

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University of Medical Sciences, School of Medicine
Street address
 No 1, Poursina St., Ghods St., Keshavarz Blvd, Tehran
City
 Tehran
Province
 Tehran
Postal code
 1417653911
Approval date
 2019-05-25, 1398/03/04
Ethics committee reference number
 IR.TUMS.MEDICINE.REC.1398.146

Health conditions studied

1

Description of health condition studied
Frontotemporal dementia

ICD-10 code
G31.0

ICD-10 code description
Frontotemporal dementia

Primary outcomes

1

Description
Changes in the lesion area of brain

Timepoint
At the commencement of the investigation and 3 months after taking inflawell

Method of measurement
MRI (Diffusion Tensor Imaging)

Secondary outcomes

1

Description
Changes in cognitive and behavioral symptoms

Timepoint
At the commencement of the investigation and 3 months after taking inflawell

Method of measurement

Clinical cognitive tests: Behavioral inventory and FTD-
Clinical dementia rating (FTD-CDR), Neuropsychiatry
inventory (NPI), Frontal assessment battery (FAB),
Persian naming test (PNT)

Intervention groups

1

Description

Intervention group: inflawell receiving group, 3 month, 3
times/day, oral administration (400 mg), inflawell
containing Boswellic acids powders was manufactured in
KondorPharma pharmaceutical Company (Canada), in
orange gelatin capsules (400 mg / capsule) and were
packed in brown containers.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Vajiheh Aghamolaie

Street address

After Lashgar Crossroads, South Kargar Street,

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9151

Email

vajiheh102@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Central university building, Qods St., Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name

Vice-Chancellor of Research Affairs, Tehran university of
medical sciences

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Vajihe Aghamolie

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vajihe Aghamolaie

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

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

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, 2024

To whom data/document is available

People working in academic institutions or people working in business

Under which criteria data/document could be used

No specific condition

From where data/document is obtainable

Vajihe Aghamolaie, Roozbeh hospital, Tehran University of Medical Sciences, Tel: 00982155419151,

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 one month.

Comments