Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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

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 buttery (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
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Tehran
Postal code
13337159140
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+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.
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Tehran
Postal code
13337159140
Phone
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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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Position
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Latest degree
Specialist
Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor

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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 businesse

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