Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The efficacy of Inflawell capsules containing Boswellic acids in patients with cognitive impairment due to traumatic brain injury: A Randomized, Double-blind Placebo-controlled Trial

Protocol summary

Study aim
Investigation of effect of Inflawell capsules containing Boswellic acids on the cognitive disorders of patients with traumatic brain injury

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

Settings and conduct
Trial will be performed in Roozbeh 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: traumatic brain injury patients Patients who are in 3 months to 3 years from the time of traumatic brain injury Exclusion criteria: Patients with uncontrollable seizures Patients with impaired level of consciousness Patients with (Glasgo outcome scale) GOS less than 3 Taking anticholinergic drugs Taking anticonvulsants and sedatives drugs Epidural hematoma, subdural hematoma and Contusion

Intervention groups
Inflawell capsules receiving group, Placebo gruop

Main outcome variables
Cognitive impairment intensity

General information

Reason for update
Correction of the details of intervention and running title

Acronym

IRCT registration information
IRCT registration number: **IRCT20170315033086N6**
Registration date: **2020-07-19, 1399/04/29**
Registration timing: **retrospective**
Last update: **2021-03-17, 1399/12/27**
Update count: **2**

Registration date
2020-07-19, 1399/04/29

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
2018-11-22, 1397/09/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
2019-01-10, 1397/10/20

Actual recruitment end date
2020-02-20, 1398/12/01

Trial completion date
2020-04-20, 1399/02/01

Scientific title
The efficacy of Inflawell capsules containing Boswellic acids in patients with cognitive impairment due to traumatic brain injury: A Randomized, Double-blind Placebo-controlled Trial

Public title

The efficacy of Inflawell capsules containing Boswellic acids in patients with cognitive impairment due to traumatic brain injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

traumatic brain injury patients Patients who are in 3 months to 3 years from the time of traumatic brain injury

Exclusion criteria:

Patients with uncontrollable seizures Patients with impaired level of consciousness Patients with (Glasgo outcome scale) GOS less than 3 Taking anticholinergic drugs Taking anticonvulsants and sedatives drugs (such as Phenytoin, Topiramate, Levetiracetam) Epidural hematoma, subdural hematoma and Contusion substance abuse Previous brain trauma Multiple sclerosis, Bipolar mood disorder, Schizophrenia, aphasia, spinal cord injury, motor disorder Lactation and pregnanacy

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is designed based on four-sized block randomization procedure. A non-ordered computer sequence list including the patient-assigned code and the order of recruitment is generated by an epidemiologist via Stata v.15 software. Given the block size of 4, there are 6 possible ways to equally assign participants to each treatment group. Therefore recruitment of participants to each treatment category is randomized and unpredictable. Following this randomization, an equal number of participants is randomly assigned to each treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient allocation and sequencing are done blindly. All the members of the staff who are involved in performing the enrollment, physicians, nurses and the investigation team as well as patients and their guardians, are masked. The research group is uninformed of drug and/or placebo prescription and its dosage. Codes will be written on the sealed envelopes and the medication bottles. Following patient assessment by the doctor, according to the admission sequence, the envelopes with the same number will be opened. Subsequently, the patients are going to be handed a bottle that could be the drug or placebo based on the assigned code. Therefore, the patient is unbeknownst whether the intervention is drug or the placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee، School of Medicine, Tehran University of Medical Sciences,

Street address

No 1, Poursina St., Ghods St., Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2018-11-10, 1397/08/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.526

Health conditions studied

1

Description of health condition studied

Traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Cognitive impairment intensity

Timepoint

At the commencement of the investigation and after taking Inflawell capsules

Method of measurement

Rey Auditory Verbal Learning Test-Recognition Test (AVLT-R), Wechsler adult intelligence Digit Symbol Substitution Test (DSST) and trail-making test part B (TMT-B)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Inflawell receiving group, 3 month, 3 times/day, Oral Administration (400 mg), Boswellic acids powder in KondorPharma Pharmaceutical Company (Canada), was encapsulated in orange gelatin capsules (400 mg / capsule) and they were packed in brown container
Category
Treatment - Drugs

2

Description
Control group: placebo receiving group, 3 month, 3 times/day, oral administration, Microcrystalline cellulose compound was also purchased under the brand name AVICEL (particle diameter: less than 50 micrometers) as placebo from Exir Pharmaceutical Company, Iran and encapsulated in Osweh Pharmaceutical Factory in orange gelatin capsules similar to the drug group (400 mg / capsule) and they were packed in brown container
Category
Placebo

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
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vajiheh Aghamolaie
Street address
After Lashgar crossroads, South Karegar Street
City
Tehran
Province
Tehran
Postal code
13337159140
Phone
+98 21 5541 9151
Email
vajiheh102@gmail.com
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?
No
Title of funding source
Vice-Chancellor of Research Affairs, Tehran university of medical sciences, 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
Street address
After Lashgar crossroads, South Karegar Street
City
Tehran
Province
Tehran
Postal code
13337159140
Phone
+98 21 5541 9151
Email
vajiheh102@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vajihe Aghamolaie

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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After Lashgar crossroads, South Karegar St.

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+98 21 5541 9151

Email
vajiheh102@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vajihe Aghmolaie

Position
Associate professor

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Email
vajiheh102@gmail.com

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, 2022

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
Vajihe Aghamolaie, Roozbeh hospital, Tehran University of Medical Sciences, Tel: 00982155419151, Mobile phone:00989133412204

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