

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Investigating the effect of Boswellia Serrata supplementation on cognitive rehabilitation following diffuse axonal injuries

Protocol summary

Summary

In a pilot, double blind, cross over clinical trial, we are going to assess the effect of boswellia serata extract on neurocognitive rehabilitation following closed head injuries. We, prospectively, recruit 40 patients admitted with initial diagnosis of diffuse axonal injury. The patients are assigned in two groups. One group will receive Boswellia serrata extract, 400mg, 3 times a day, while the other group will receive placebo for 6 weeks. Then, the patients will be crossed over alternative intervention for another 6 weeks period. Neuro-cognitive function tests including Disability Rating Scale (DRS), the Glasgow outcome Scale/Extended (GOSE), and the Mini-mental Status Test (MMSE) are applied 1-2 weeks, 6 weeks, and 12 weeks after beginning of the intervention.

Email address

h_moin@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2009-11-30, 1388/09/09

Expected recruitment end date

2010-09-01, 1389/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804082093N1**

Registration date: **2009-11-30, 1388/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-11-30, 1388/09/09

Registrant information

Name

Payam Moin

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1629 0630

Scientific title

Investigating the effect of Boswellia Serrata supplementation on cognitive rehabilitation following diffuse axonal injuries

Public title

Investigating the effect of Boswellia Serrata, a kind of herbal remedy on cognitive impairments following closed head injuries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 15 – 55 years old, stable Vital signs, Glasgow Coma Scale score of 12 or less within the first 24 hours of injury, Post traumatic amnesia of at least 24 hours, loss of consciousness immediately after motor vehicle crash, subjects with no known life-threatening or unstable dangerous disease before head injury, ability to receive medication orally or by nasogastric tube, no active severe infection
Exclusion criteria: pregnancy breast feeding, Multiple traumas that may impair the accuracy of results, penetrating head injury, receiving chronic asthmatic, anticancer, antifungal, anti-

inflammatory pain relievers, immunomodulators, or sedatives, Prior significant TBI, brain tumor, cerebral vascular event, other stable brain insults, Prior history or familial history of any severe allergic or atopic disease, The presence of any severe or progressive lesion such as intracranial hematoma that would lead to open cranial surgery after injury, Any acute disturbance in vital signs or laboratory data being or not being attributable to boswellia extract, or any cutaneous or other organ lesions which may imply allergic reaction, history of severe psychological disorder in which cognitive functions are impaired like mental retardation or dementia, Patients undergone brain surgery after or before trauma, Refractory and severe vomiting, past history or laboratory data suggesting liver or renal disease

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Daneshgah St., Isfahan, Iran

City

Isfahan

Postal code**Approval date**

2009-12-15, 1388/09/24

Ethics committee reference number

288262

Health conditions studied**1****Description of health condition studied**

Diffuse axonal Injury

ICD-10 code

S06.2

ICD-10 code description

Traumatic compression of brain NOS

Primary outcomes**1****Description**

Glasgow Outcome Scale Extended score

Timepoint

2, 6 and 12 weeks after admission

Method of measurement

physical exam and history

2**Description**

Glasgow Coma Scale score

Timepoint

First day of admission, and 2, 6, and 12 weeks later

Method of measurement

Physical exam

3**Description**

Disability Rating Scale score

Timepoint

2, 6 and 12 weeks after admission

Method of measurement

Physical exam and history

4**Description**

Mini-Mental State Examination score

Timepoint

2, 6 and 12 weeks after admission

Method of measurement

Physical exam and history

Secondary outcomes**1****Description**

Duration of admission

Timepoint

Number of days from admission to discharge

Method of measurement

follow up

2**Description**

Coma duration

Timepoint

from admission until Glasgow Outcome Scale score overgoes 9

Method of measurement

physical exam

Intervention groups

1

Description

Boswellia Serrata medical compound (400 mgr, three times daily, per oral, for 6 weeks

Category

Treatment - Drugs

2

Description

Placebo(TDS,PO)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra and Kashani hospitals

Full name of responsible person

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Research, Isfahan University of Medical Sciences

Full name of responsible person

Peyman Adibi, MD

Street address

Hezar Jarib St.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellery for Research, Isfahan 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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Payam Moin

Position

Medical student

Other areas of specialty/work

Street address

6th floor, No. 10, Sepehar building, Yahyakan alley, Chaharbagh bala street

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Houshang Moin

Position

Full Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan university of medical sciences

Full name of responsible person

Payam Moin

Position

Internship (medical student)

Other areas of specialty/work**Street address**

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Fax**Email**

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Web page address**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