Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Clinical trial phase II of oral hebal compoenent (BMP) in patient with multiple sclerosis

Protocol summary

Summary

This is a phase II clinical trial for safety and efficacy of herbal drug(BMP) in Multiple Sclerosi . In this study ten patients with the diagnosis of Multiple sclrosis who had not respond to standard treatment will be recruited. Patients will take oral herbal component as capsules. Each cap containes 500mg active ingredient from Xanthins and the source herb is a kind of pepper and ; patients take 4 cap a day for six months and will follow for six months afterend of treatment . The treatment with the drug will add to standard treatment. Primary outcomes are changes in MRI and secondary outcomes are EDSS and MSIS quality of life questionaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803241696N2**
Registration date: **2009-09-26, 1388/07/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name
Shahriar Nafissi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8490 2224
Email address
nafisi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran Rheumatism Center

Expected recruitment start date

2009-06-14, 1388/03/24

Expected recruitment end date

2009-09-14, 1388/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial phase II of oral hebal compoenent (BMP) in patient with multiple sclerosis

Public title

Clinical trial phase II of oral hebal compoenent (BMP) in patient with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 50 Multiple sclerosis diagnosis by Mac Donald criteria EDSS more than six Signing informed consent Exclusion criteria: Sever hepatic/ Renal or cardiac diease Sever psychological disorders Adminstration of IVIG, Mitoxantrone, Plasmapheresis or immunosupressive drug since three months before Pegnancy or intention to pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

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
Ethice Committee of Endocrinology and Metabolism Research Center

Street address
Fifth Floor, Shariati Hospital, North Kargar St., Tehran, Iran

City
Tehran

Postal code
14114

Approval date
2009-04-21, 1388/02/01

Ethics committee reference number
E-0034

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35, G36,

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Changes in MRI (Magnetic Resonance Imaging)

Timepoint
start of treatment, 6th and 12th month

Method of measurement
Magnetic Resonance Imaging

Secondary outcomes

1

Description
EDSS

Timepoint
Start of Treatment, 1st, 2nd, 3rd, 4th, 5th, 6th, 8th, 10th, and 12th month

Method of measurement
Asking from patients

2

Description
MSIS quality of life questionnaire

Timepoint
Start of Treatment, 1st, 2nd, 3rd, 4th, 5th, 6th, 8th, 10th, and 12th month

Method of measurement
Completing the questionnaire

Intervention groups

1

Description
BMP oral capsules, each containes 500 mg active ingredient

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Rheumatism Center

Full name of responsible person
Dr. Shahryar Nafisi

Street address
Shariaty Hospital, North Kargar st., Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran Rheumatism Center

Full name of responsible person
Dr Shahriar Nafisi

Street address
No.9, khosravi Alley, North Kargar st., Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Rheumatism Center
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
Shariati hospital, Tehran University of Medical Sciences, Tehran, Iran
Full name of responsible person
Dr. Shahryar Nafisi
Position
Associate professor
Other areas of specialty/work
Street address
Shariati hospital, North kargar st., Tehran, Iran
City
Tehran
Postal code
14114
Phone
Fax
Email
nafisi@sina.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shariati hospital, Tehran University of Medical Sciences, Tehran, Iran
Full name of responsible person
Dr. Shahryar Nafisi
Position
Associate Professor
Other areas of specialty/work
Street address
Shariati hospital, North kargar st., Tehran, Iran
City
Tehran
Postal code
14114
Phone
Fax
Email
nafisi@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shariati hospital,Tehran University of Medical Sciences, Tehran, Iran
Full name of responsible person
Dr. Shahryar Nafisi
Position
Associate professor
Other areas of specialty/work
Street address
Shariati hospital, North kargar st., Tehran, Iran
City
Tehran
Postal code
14114
Phone
Fax
Email
nafisi@sina.tums.ac.ir
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