Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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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

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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
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Other areas of specialty/work
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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