Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical evaluation of the effect of Jadwar (Delphinium denudatum) capsules on quality of life and fatigue of multiple sclerosis patients

Protocol summary

Study aim
Evaluation of the effect of Jadwar on quality of life and fatigue of multiple sclerosis patients

Design
Randomized, double-blind, placebo-controlled clinical trial; phase 2-3; with control and intervention groups, with parallel groups.

Settings and conduct
This study will be performed on MS patients in Khuzestan Province who are supported by the Khuzestan MS Association. Patients will receive routine daily treatment. These patients will be randomly divided into two groups who will randomly receive a placebo or herbal capsule. Unique codes provided by the software will be used on medicine boxes. To assess patients at the beginning and end of the intervention, quality of life and fatigue are assessed by MSQOL-54 and Fatigue Severity Scale (FSS) questionnaires.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Proven MS according to clinical examinations and medical history, having stable and regular drug treatment in the last 4 weeks, having a score of EDSS disability assessment between 2 to 5.5 Exclusion criteria: pregnancy and lactation, Renal and hepatic dysfunction, neurological disease in addition to MS, Allergy to Jadwar

Intervention groups
Patients are randomly assigned to treatment and control groups. The treatment and control groups receive the capsule of Jadwar (500 mg) or placebo once a night at bedtime for 12 weeks.

Main outcome variables
Quality of life (MSQOL-54 questionnaire); Fatigue (FSS questionnaire).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200128046288N5**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **prospective**

Last update: **2020-11-19, 1399/08/29**
Update count: **0**

Registration date
2020-11-19, 1399/08/29

Registrant information

Name
Fereshteh Golfakhrabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3373 8378

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golfakhrabadi-f@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical evaluation of the effect of Jadwar (Delphinium denudatum) capsules on quality of life and fatigue of multiple sclerosis patients

Public title
Effect of Jadwar capsules in multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
MS has been proven by clinical examinations and medical history Having stable and regular drug treatment in the last 4 weeks No new attack in last month Having a score of EDSS disability assessment between 2 to 5.5
Exclusion criteria:
Pregnancy and lactation Renal and hepatic dysfunction Neurologic disease in addition to MS Cardiovascular disease or infectious disease Allergy to Jadwar
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is used. Because we have two intervention groups, equal 4 blocks is used and all 4 possible modes is created and then with Excel software we randomly select a number of blocks. Label of the medications is one of the letters A or B and the sequence of randomization determined by the statistical consultant. For allocation concealment, drug delivery and the sequence of randomization is not performed by researchers and evaluators while is the responsibility of another individual .
Blinding (investigator's opinion)
Double blinded
Blinding description
Unique codes, which is generated by the software, will be used on the drug and placebo boxes. By entering each individual into the study based on the produced sequence, the drug or placebo box in which the code is registered, are assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators are not aware of the assigned groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2020-10-31, 1399/08/10
Ethics committee reference number
IR.AJUMS.REC.1399.624

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

2

Description of health condition studied
Fatigue
ICD-10 code
F48.0
ICD-10 code description
Fatigue

Primary outcomes

1

Description
Fatigue rate
Timepoint
The first day of intervention and three months later
Method of measurement
FSS questionnaires

2

Description
Quality of Life
Timepoint

The first day of intervention and three months later

Method of measurement

Questionnaire MSQL54

Secondary outcomes

1

Description

Side effects of the drug

Timepoint

Three months after the start of the intervention

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Capsule of Jadwar 500 mg once daily for three months

Category

Treatment - Drugs

2

Description

Control group: Capsule of placebo once daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital in Ahvaz

Full name of responsible person

Fereshteh Golfakhrabadi

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Ahvaz Jundishapur University of Medical Sciences, Golestan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghaddam

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fereshteh Golfakhrabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data will be shared

When the data will become available and for how long
The access time is up to 6 months after the results are published

To whom data/document is available
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis

Under which criteria data/document could be used
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

From where data/document is obtainable
Applicants can email the responsible author to receive the requested data golfakhrabadi@yahoo.com

What processes are involved for a request to access data/document
Applicants will have access to the data from the present study by emailing the responsible author for up to one month. golfakhrabadi@yahoo.com

Comments