

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 61 3373 8378

Email address

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 MSQ154

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,
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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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Position

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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