Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy and safety of “Jollab monzej” as a traditional Persian compound medicine for the treatment of multiple sclerosis-related fatigue: A randomized placebo-controlled trial

Protocol summary

Study aim

Determination of efficacy and safety of “Jollab monzej” as a traditional Persian compound medicine for the treatment of multiple sclerosis-related fatigue compared with placebo

Design

56 participants in phase 3, double-blind parallel group, randomized clinical trial with outcome assessment, based on random sheets of code in sealedenvelope site, were assigned to either the drug or placebo intervention groups.

Settings and conduct

The study runs after approval of the proposal, registration with research center and permission from the Ethics Committee, and registration with the Center Iran's clinical trial.Patients with multiple sclerosis, referred to the neurologist's office and Iran MS society, were randomly divided into two intervention groups, based on inclusion and exclusion criteria.FSS, PSQI, BDI and VAS questionnaires are completed for each individual at the bigining and end of one month (completion of treatment) and also two week after that, again.

Participants/Inclusion and exclusion criteria

Inclusion criteria -Multiple sclerosis (MS) patients, female or male -Age range 18-55 years -Patients with relapsing-remitting MS -MS patients with EDSS ≤ 6 -MS patients are suffering from fatigue -Fatigue score ≥ 36 on the FSS questionnaire -Consent to participate in the study No inclusion criteria -Pregnancy and lactation -The comorbidity of severe and chronic disease -known active infection -Suffering from psychosis or dementia -Depression in BDI questionnaire -Patients with a change in main drug of MS, over the past three months -Patients with relapse or consumption of corticosteroids, over the past three months

Intervention groups

In this study, drug group receive, the traditional persian compound medicine, and placebo group, consume a product; containing a small amount of one component of the drug.

Main outcome variables

Jollab-e-monzej; Fatigue

General information

Reason for update

In the study implementation phase due to the intersection of participants recruitments of the study with the prevalence of COVID-19, and considering the completion of the sample size of the study fatigue section, the research team decided to end the study to prevent possible complications of the intervention due to uncertain conditions and effects of coronavirus in MS patients. , and evaluate the efficacy and safety of the traditional medicine product on MS fatigue as a primary outcome and insomnia as a secondary outcome. Based on this, changes were made in the title and sample size of the study, which are reported.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190623043984N1**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**
Update count: **1**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

Fatemeh Yousefnia babaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone
+98 21 8877 3521
Email address
fyousefnia@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-21, 1398/11/01
Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date
2020-01-21, 1398/11/01
Actual recruitment end date
2020-04-15, 1399/01/27
Trial completion date
2020-04-15, 1399/01/27

Scientific title
Efficacy and safety of “Jollab monzej” as a traditional Persian compound medicine for the treatment of multiple sclerosis-related fatigue: A randomized placebo-controlled trial

Public title
Effect of "Jollab-e-monzej" for the treatment of MS-related fatigue
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
-Multiple sclerosis patients, female or male -Age range 18-55 years -Patients with relapsing-remitting MS -MS patients with EDSS of less than or equal to 6 -MS patients are suffering from fatigue and insomnia -Fatigue score greater than or equal to 36 on the FSS questionnaire -Consent to participate in the study
Exclusion criteria:
-Pregnancy and lactation -The comorbidity of severe and chronic disease -known active infection -Suffering from psychosis or dementia -Depression in BDI questionnaire -Patients with a change in main drug of MS over the past three months -Patients with relapse and/or consumption of corticosteroides over the past three months
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
After calculating the final sample size of the study, Random chains are generated based on simple random series using permuted block at sealedenvelope site for two intervention and comparison groups. Then a matched code will be generated for each sequence, based on random chain, which contains two letters of the alphabet and one number.The anonymous code is pasted on the study drugs (research label) before starting the study and also are stored.During the study, patients are given medication, according to the sequence of patient's entry and randomization sheets (containing only anonymous codes) of the medications stored.Therefore, the research drug distributors and participants in the study are blinded to the assigned group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researcher who performs process, is also clinical caregiver and outcome evaluator that assigns participants based on randomization codes sheets into two groups; intervention medication group and intervention placebo group.During the study, patients are given medication, according to the sequence of patient's entry and randomization sheets (containing only anonymous codes) of the medications stored.Therefore, the research drug distributors and participants in the study are blinded to the assigned group. The pharmacist as well as the data analyzer get inform about group assignment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Shahid Beheshti University of medical Sciences
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak,Shahid Beheshti University of medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-03-17, 1397/12/26
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.1395

Health conditions studied

1

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

Primary outcomes

1

Description
Fatigue score on the fatigue severity scale questionnaire
Timepoint
Measurement of fatigue score at baseline and after one month (intervention period) and also two weeks after intervention period
Method of measurement
Fatigue severity scale questionnaire

Secondary outcomes

1

Description
Fatigue score on the visual analogue score
Timepoint
Measurement of fatigue score at baseline and after one month (intervention period) and also two weeks after intervention period
Method of measurement
The Visual analogue scale (VAS)

2

Description
Global sleep quality score on the PSQI questionnaire
Timepoint
Measurement of global sleep quality score at baseline and after one month (intervention period) and also two weeks after intervention period
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI)

3

Description
Depression score on BDI questionnaire
Timepoint
Measurement of depression score at baseline and after one month (intervention period) and also two weeks after intervention period
Method of measurement
Beck depression inventory questionnaire (BDI)

Intervention groups

1

Description
Intervention group: Intervention group 1: Jollab-e-monzej syrup, which the participants consume in the morning and evening, 20 to 30 ml, depending on their weight, for one month.
Category
Treatment - Drugs

2

Description
Control group:Intervention group 2: Placebo syrup, which the participants consume in the morning and evening, 20 to 30 ml, depending on their weight, for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Private clinic
Full name of responsible person
Dr. Kurosh Gharagozli
Street address
No. 151, Jamalzadeh Street, Keshavarz Boulevard, Tehran, Iran
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2

Recruitment center
Name of recruitment center
private clinic
Full name of responsible person
Dr. Abdorreza Naser Moghadasi
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Iran, Tehran, Keshavarz Boulevard, 16 Azar St., 16 Azar Clinic
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3

Recruitment center

Name of recruitment center
Iran MS society

Full name of responsible person
Dr. Abdorreza Naser Moghadasi

Street address
No. 35, Shahid Mohammad Shams Alley, Tesghani Intersection, Vesal Shirazi St., Enghelab St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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1985717443

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fatemeh Yousefnia Babaki

Position
MD, Ph.D student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences, No. 8, Shams Alley, Valiasr Ave., Tehran, Iran

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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

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Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available