# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of Saffron syrup on fatigue severity in patient with multiple sclerosis

## Protocol summary

**Summary**

This study as a before-after study, aims to investigate the effect of saffron syrup on reducing fatigue in patients with multiple sclerosis (MS). So the sample size of 30 people who have had a history of the disease for at least 6 months and do not use anti-depressant drugs will be selected as available and will be evaluated according to the Fatigue Severity Scale (FSS). Patients who have moderate to severe fatigue based on this scale will be included in the study. Participants in this study take a tablespoon of saffron syrup every 8 hours for two months. After 60 days of drug administration, patients are again evaluated for fatigue to determine how effective the drug is in reducing their fatigue.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017061226667N6**
Registration date: **2017-08-04, 1396/05/13**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-08-04, 1396/05/13

**Registrant information**

**Name**

Ali Jadidi

**Name of organization / entity**

Arak University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3417 3508

**Email address**

jadidi@arakmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Arak University of Medical Sciences

**Expected recruitment start date**

2017-08-06, 1396/05/15

**Expected recruitment end date**

2018-04-17, 1397/01/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Saffron syrup on fatigue severity in patient with multiple sclerosis

**Public title**

Effect of saffron syrup on fatigue severity

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Having a history of MS for 6 months; Age 15 to 60 years; The desire to enter the study; Not pregnant; Not having diabetes. Exclusion criteria: Unwillingness to continue the study; Use of antidepressants; Use of other effective drugs for the relief of fatigue (Ritalin, Pamolin and Amantadine); Treated by other methods such as physical therapy and occupational therapy.

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**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**

Ethics committee of Arak University of Medical Sciences

**Street address**

Arak University of Medical Sciences, Basij square, Taleghani Avenue.

**City**

Arak

**Postal code**

**Approval date**

2017-06-24, 1396/04/03

**Ethics committee reference number**

IR.ARAKMU.REC.1396.68

## 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 severity

**Timepoint**

Before the intervention and two months after the intervention

**Method of measurement**

Questionnaire of Fatigue Severity Scale (FSS)

## Secondary outcomes

**1**

**Description**

-

**Timepoint**

-

**Method of measurement**

-

## Intervention groups

**1**

**Description**

Take a tablespoon of saffron syrup every 8 hours for two months.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Amir Al-Momenin Hospital

**Full name of responsible person**

Ali Khan Mohammadi

**Street address**

Sardasht Square, Taleghani Street

**City**

Arak

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

**Full name of responsible person**

Ali Jadidi

**Street address**

Sardasht Square, Taleghani Street, Arak University of Medical Sciences, Arak

**City**

Arak

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice chancellor for research, Arak University of Medical Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Reza Rezai Ashtiani

**Position**

Neuorologist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

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Ali Khan Mohammadi

**Position**

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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*