

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

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##### 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.

##### 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

#### 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

##### 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**

Neurologist

**Other areas of specialty/work**

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Seyyed Amir Hossein Latifi

**Position**

PhD of Traditional Medicine

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Arak University of Medical Sciences

**Full name of responsible person**

Ali Khan Mohammadi

**Position**

Bachelor of Nursing

**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*