

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effects of Melatonin on radiological changes of multiple sclerosis patient

#### Protocol summary

##### Summary

Aim of this study is effects of Melatonin on radiological changes of multiple sclerosis patient. This study is clinical trials and double blind with placebo. 60 patient with multiple sclerosis with collaboration of the Multiple Sclerosis Society Province will be selected randomly. Inclusion criteria: multiple sclerosis with Mc.donald score; 18 to 50 years; Expanded Disability Status Scale (EDSS) 0 to 5.5. Exclusion criteria: pregnancy; use pulse Corticosteroids drug in 6 months ago; lack of routine monitoring of patients; attack during the study; antioxidant use in the last 3 months. We prescribe drug for controlling multiple sclerosis (Interfron) for all patients. We prescribe 3 milligram Melatonin for 12 weeks in intervention group and placebo for 12 weeks in control group. We check patients with MRI from the point of view T1, T2, GAD Plaques in start of study and 3 months after treatment

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##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2015-04-26, 1394/02/06

##### Expected recruitment end date

2017-08-28, 1396/06/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072520258N56**

Registration date: **2017-07-26, 1396/05/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-26, 1396/05/04

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

##### Scientific title

Effects of Melatonin on radiological changes of multiple sclerosis patient

##### Public title

Effects of Melatonin on radiological changes of multiple sclerosis patient

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: multiple sclerosis with Mc.donald score; 18 to 50 years; Expanded Disability Status Scale (EDSS) 0 to 5.5. Exclusion criteria: pregnancy; use pulse Corticosteroids drug in 6 months ago; lack of routine monitoring of patients; attack during the study; Antioxidant use in the last 3 months

##### Age

From **18 years** old to **50 years** old

##### Gender

Female

##### Phase

2-3  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: 58  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee Arak University Of Medical Sciences

##### Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Postal code

38149578558

#### Approval date

2015-07-22, 1394/04/31

#### Ethics committee reference number

IR.ARAKMU.REC.1394.7

## 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

number of T1,T2, GAD Plaques

#### Timepoint

start of study and 3 months

#### Method of measurement

MRI

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: We prescribe 3 milligram Melatonin every night for 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

In control group: We prescribe placebo for 12 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Multiple Sclerosis Society Province in Arak

##### Full name of responsible person

Dr Fardin Faraji

##### Street address

Shahid Rajaei ,Arak

##### 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

Dr Anoshirvani

##### Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, 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***Phone**

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**Email**

faraji@arakmu.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Aliakbar Maleki rad

**Position**

Faculty member

**Other areas of specialty/work****Street address**

Shahid Shirodi street, Valiasr square, Valiasr hospital

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

medicine student

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Arak University of Medical Sciences

**Full name of responsible person**

Dr Fardin Faraji

**Position**

Faculty, Neurologist

**Other areas of specialty/work****Street address**

Shahid Shirodi street, Valiasr square, Valiasr hospital

**City**

Arak

**Postal code**

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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*