

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Melatonin on the disability of multiple sclerosis patients

Protocol summary

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Summary

Aim of this study is effect of Melatonin on fatigue in Multiple sclerosis in Valiasr hospital. This study is clinical trials and double blind with placebo. 60 patient with multiple sclerosis in collaboration of 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; side effect of drug. We prescribe Interfron for controlling multiple sclerosis for all patients. We prescribe 3 milligram Melatonin for 12 weeks in intervention group and placebo for 12 weeks in control group. We use expanded disability status scale (EDSS). We check patients before treatment and 12 weeks after treatment by neurologist.

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-04-25, 1394/02/05

Expected recruitment end date

2017-08-27, 1396/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072520258N55**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

Scientific title

The effect of Melatonin on the disability of multiple sclerosis patients

Public title

The effect of Melatonin on the disability of multiple sclerosis patients

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; side effect of drug; lack of routine monitoring of patients.

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

2015-04-20, 1394/01/31

Ethics committee reference number

IR.ARAKMU.REC.1394.9

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

disability

Timepoint

before treatment and 12 weeks after treatment

Method of measurement

Disability Status Scale (EDSS)

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

Treatment - Drugs

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 Rajaee ,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

Person responsible for general inquiries

Contact

Name of organization / entity
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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