Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Melatonin on Fatigue in Multiple sclerosis patients

Protocol summary

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 with collaboration of the Multiple Sclerosis Society Province will be selected randomly. Inclusion criteria are including multiple sclerosis with Mc.Donald score; 18 to 50 years; Expanded Disability Status Scale (EDSS) 0 to 5.5; multiple sclerosis with IFN-B. Exclusion criteria: pregnancy; patients with acute attack in 3 months ago; lack of routine monitoring of patients. We prescribe drug for controling multiple sclerosis (Interfron) for all patients. We prescribe 3 milligram Melatonin for 8 weeks in intervention group and placebo for 8 weeks in control group. We use standard fatigue questionnaire (FSS) for fatigue. We check patients before treatment and 8 weeks after treatment by neurologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030120258N35**
Registration date: **2017-04-27, 1396/02/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-27, 1396/02/07

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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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and research, Arak University of Medical Sciences

Expected recruitment start date

2015-06-09, 1394/03/19

Expected recruitment end date

2016-06-08, 1395/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Melatonin on Fatigue in Multiple sclerosis patients

Public title

The effect of Melatonin on Fatigue in 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; multiple sclerosis with IFN-B. Exclusion criteria: pregnancy; patients with acute attack in 3 months ago; 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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
City
Arak
Postal code
38149578558
Approval date
2015-06-08, 1394/03/18
Ethics committee reference number
IR.ARAKMU.REC.1394.51

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
Timepoint
before treatment and 8 weeks after treatment
Method of measurement
standard fatigue questionnaire (FSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We prescribe 3 milligram Melatonin every night for 8 weeks.
Category
Treatment - Drugs

2

Description
In control group: We prescribe placebo for 8 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 Mohammad Rafiee
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
Arak University of Medical Sciences
Full name of responsible person
Dr Fardin Faraji
Position
Faculty, Neurologist
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Person responsible for updating data

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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