Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 controling 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

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
+98 86 3222 2003
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

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 squre, 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 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
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
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
malekirad@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
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 squre, Valiasr hospital
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
faraji@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mobina aghaalamdar
Position
medicine student
Other areas of specialty/work
Street address
Payambar Azam Complex, Basij Square, Sardasht, Arak
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
mobina.alamdar@gmail.com
Web page address

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