Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of Melatonin on sphincter disorder(urinary symptoms) in multiple sclerosis

Protocol summary

Summary

Aim of this study the effect of melatonin on sphincter disorder(urinary symptoms) in multiple sclerosis. This study is clinical trials and three blind with placebo.60 patient with multiple sclerosis with collaboration with the Multiple Sclerosis Society Province select randomly. Inclusion criteria: multiple sclerosis with Mc.donald score; 18 to 50 years; 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 control multiple sclerosis (Interfron) for all patients. We prescribe 3 milligram Melatonin for 8 week in intervention group. We prescribe placebo for 8 week in control group. We use standard questionnaire urodynamic study of urinary disorders. We check patients before and after 8 week by nurologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022620258N34**
Registration date: **2017-03-09, 1395/12/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-09, 1395/12/19

Registrant information

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Fariba Farokhi
Name of organization / entity
Arak University of Medical Sciences
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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

2017-06-09, 1396/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of Melatonin on sphincter disorder(urinary symptoms) in multiple sclerosis

Public title

the effect of Melatonin on sphincter disorder in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: multiple sclerosis with Mc.donald score; 18 to 50 years; 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

Both

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)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomize with 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.1394.45

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

urinary disorder

Timepoint

before and after 8 week

Method of measurement

standard questionnaire urodynamic

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:We prescribe 3 milligram Melatonin and Interfron for 8 weeks for 30 patients.

Category

Treatment - Drugs

2

Description

Control group:We prescribe placebo and Interfron for 8 weeks for 30 patients.

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

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Dr Mohammad Rafiee, 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

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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