

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of aspirin and placebo for the treatment of fatigue in multiple sclerosis

Protocol summary

Study aim

Comparison of the effect of aspirin and placebo for the treatment of fatigue in multiple sclerosis

Design

Clinical randomized trial with control group ,parallel,triple blind strains,randomized phase3 (40patients)

Settings and conduct

After obtaining informed consent, the FSS questionnaire is given to the patients referred to the private practice or the clinic of Shahid Beheshti Hospital in Kashan, who complain of fatigue, and if they score 4, they are entered into the study. Then the patients are randomly divided into two groups, the first group includes 20 patients with aspirin 325 mg. And the second group, which consists of 20 patients, will be given a placebo. After 6 weeks, the MFIS and FSS questionnaires will be filled again for the patients, and the filled initial questionnaire will be compared. Medicines are made and prepared in the same packaging and appearance and size at Barij Essan Pharmaceutical Company. Then they are used based on the codes that were previously prepared using a table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with multiple sclerosis (age between 18-55 years old) who suffer from fatigue
Exclusion criteria: hx of GI bleeding or GI ulcer, pregnancy, Attack of disease in the last 4 weeks (and use of corticosteroid), continuous use of aspirin or NSAID for 4 weeks before the study, consumption of alcohol and drugs, EDSS > 6

Intervention groups

40 patients with multiple sclerosis are divided into two groups. One group is given aspirin 325 mg daily and the other group (control group) is given medicine (aspirin 325 mg)

Main outcome variables

Fatigue of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230802059008N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Mahtab Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 1057

Email address

mahtabkarami303@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aspirin and placebo for the treatment of fatigue in multiple sclerosis

Public title

Effect of aspirin in fatigue of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

FSS score ≥ 4 EDSS ≤ 6 Patients with multiple sclerosis (age between 18_55)

Exclusion criteria:

Depression Hypothyroidism Pregnancy Anemia
Thrombocytopenia Hx of GI bleeding ,GI ulcer Asthma
Alcohol use MS attack in the last 4weeks that
corticosteroid used for treatment Chronic renal disease
Chronic pulmonary disease Chronic metabolic disease
Chronic heart disease

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by block method with a number of blocks in phase, starting with all of the 4 blocks, including A and B, which can be easily configured (4 blocks), using a random number table. The random blocks must be selected (26 blocks). 4tai A and B are a combination of these, as they are coincidental, so that they are different from each other. After entering the study ,patients will receive one of the drugs according to the code(from 1to 104) that is registered on the drug's lable.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drugs are prepared in the same size and packaging in Barij Essence Pharmaceutical Company. Then they are coded using previous random numbers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd,Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.058

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

severity of fatigue

Timepoint

Measuring the intensity of fatigue at the beginning of the study (before the start of the intervention) and 42 days after taking aspirin 325 mg and placebo (at the end of the study - 6 weeks later)

Method of measurement

Fatigue severity scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients are treated with aspirin 325 mg (Produced by Pars Daru Company)daily. The patients are given the necessary training in case of possible side effects related to aspirin. It is available to the patients to contact in case of problems, and then the patients are contacted every two weeks to follow up on the regular use of medicines

Category

Treatment - Drugs

2**Description**

Control group:20 patients will be treated with placebo daily.placebo is formed by Barij Essans pharmaceutical company with combination of oisel and wheat starch .It is given in the form of a tablet of the same size as aspirin.each patient uses the medicine once a day.at the beginning of the study ,the patients are given the necessary training in case of possible side effects related to medicine and then the phone number to call in case of problems.then the patients are connected once every two weeks to follow up on the regular use of drugs.

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Shahid Beheshti hospital of Kashan

Full name of responsible person

Mahtab Karami

Street address

Ghotb Ravandi Blvd,Shahid Beheshti hospital

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

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

Kashan University of Medical Sciences

Full name of responsible person

Mahtab Karami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mahtab Karami

Position

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Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available