

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of clarithromycin on IL-6 serum level in patients with multiple sclerosis: A randomized, double-Blind, crossover, placebo-controlled pilot study

Protocol summary

Study aim

Evaluation of the effect of clarithromycin on improving quality of life and modification of inflammatory factor (IL-6)

Design

A randomized, double-Blind, crossover, placebo-controlled pilot study

Settings and conduct

Patients are randomly assigned to receive either clarithromycin or placebo tablet twice daily for 14 days. Subsequently, after a 1-month washout, they were crossed over to the other group during the course of the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 60 years Confirmed diagnosis of primary progressive MS No medical history of allergy to clarithromycin Exclusion criteria: Pregnancy and lactation Serious underlying medical conditions (e.g malignancy, renal and hepatic failure) Known hypersensitivity to clarithromycin and excipients Significant signs of depression

Intervention groups

MS patients were randomly assigned to receive either clarithromycin (500mg) or placebo tablets twice daily for 14 days. Subsequently, after a 1-month washout, they were crossed over to the other group during the course of the trial.

Main outcome variables

Evaluation of clarithromycin on interleukin six serum level and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100119003106N40**

Registration date: **2020-07-10, 1399/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-10, 1399/04/20**

Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 0037

Email address

hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clarithromycin on IL-6 serum level in patients with multiple sclerosis: A randomized, double-

Blind, crossover, placebo-controlled pilot study

Public title
Evaluation of clarithromycin on IL-6 serum level in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 60 years Confirmed diagnosis of primary progressive progressive MS No medical history of allergy to clarithromycin
Exclusion criteria:
Pregnancy and lactation Serious underlying medical conditions (e.g malignancy, renal and hepatic failure) Known hypersensitivity to clarithromycin and excipients Significant signs of depression

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
28 envelopes are prepared with 14 active and 14 placebo cards and shuffled. Patients are allocated the next study number (1-28) in sequence after opening the sealed envelopes to either drug or placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients, physicians, researcher and data collector (student) don't know about who was receiving the actual drug and who receiving a placebo. The informed consent was obtained from patients and they were informed that they could leave the trial at any time. The coding of the medicine boxes was done by a third party who was not involved in the study and at the end of the study, decryption took place.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran
Medical Sciences

Street address

No 99, Yakhchal street, Gholhak, Dr Shariati street

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2019-11-20, 1398/08/29

Ethics committee reference number

IR.IAU.TMU.REC.1398.135

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

Interleukin 6

Timepoint

Before intervention, week 2, 6 and 8 after intervention

Method of measurement

ELISA Kit

2

Description

Quality of life

Timepoint

Before intervention, week 2, 6 and 8 after intervention

Method of measurement

The quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

MS patients were randomly assigned to receive either clarithromycin (500mg) or placebo tablets twice daily for 14 days. Subsequently, after a 1-month washout, they

were crossed over to the other group during the course of the trial.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Dr. Saeed Shahbeigi

Street address

No. 24, Erfan building, Komijani Ave, Haft-hoz sq.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Farshad Hashemian

Street address

No. 99, Yakhchal street, Dr. Shariati Avenue, Tehran,
Iran

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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

Islamic Azad University

Proportion provided by this source

10

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Ghazal Amiri

Position

Pharm. D., candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

Position

Pharm.D., BCPS, Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ghazal Amiri

Position

Pharm. D. candidate

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All the data potentially can be shared after being unidentifiable.

When the data will become available and for how long

Just after the article's publication.

To whom data/document is available

For all investigators.

Under which criteria data/document could be used

No more information.

From where data/document is obtainable

Applicants can refer to the Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran Medical Sciences, Islamic Azad University, Dr.Hashemian or contact the researcher by sending email to ghazalamiri1995@gmail.com or calling 09120680122.

What processes are involved for a request to access data/document

Applicants can apply for research information by visiting the department or by contacting the e-mail address and telephone number as well as providing information on academic studies and the purpose of requesting the information. Applicants must commit themselves to mention the source. If the request is sent six months after the publication of the research information, the researcher will send the data to the requesting party by email within a week.

Comments

There is no more information.