

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Therapeutic and safety of clemastine fumarate in symptoms and quality of life in secondry Relapsing MS patients

Protocol summary

Study aim

Evaluation of Therapeutic and safety of clemastine in symptoms and quality of life in secondry Relapsing MS patients. and Achieving a beneficial, cheap, and less side effect drug.

Design

Clinical trial with control group, double-blind, randomized. The research included a group of 60 people receiving clemastine and group of 60 people receiving placebo.

Settings and conduct

This study is done in the neurology center, baghiatollah clinic, theran, iran. study is double-blind, randomized. The two groups received the drug and placebo for 12 weeks every 12 hours and then responded to the questionnaires.

Participants/Inclusion and exclusion criteria

inclusion criteria: sign informed consent, The patient is not at the same time in another clinical study. The patient is between 18 and 50 years of age. The patient's sex is not important. Exclusion criteria: The pregnant patient can not be selected

Intervention groups

The intervention group contains the drug clemastine fumarate, and the control group is placebo

Main outcome variables

Antibody level changes: quality of life score: clinical signs before and after research

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N40**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **retrospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2019-05-19, 1398/02/29

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2019-05-19, 1398/02/29

Trial completion date

2019-05-19, 1398/02/29

Scientific title

Evaluation of Therapeutic and safety of clemastine fumarate in symptoms and quality of life in secondry Relapsing MS patients

Public title

Evaluation of Therapeutic and safety of clemastine fumarate in symptoms and quality of life in secondry Relapsing MS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
inclusion criteria : To sign the consent form knowingly. At the same time, not in another clinical study. The patient is between 18-50 years old. only have a secondary recurrent MS.

Exclusion criteria:
The patient is pregnant

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **120**
Actual sample size reached: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control group, randomize using, random number

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is done in double blind ways, in which both the researcher and the patient do not know if they received drug or placebo. but it is explained to the patient who is participating in the study and may receive a drug or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic azad University of medical science

Street address
yasaman alley, yakhchal Street, shariati Street

City
Tehran

Province
Tehran

Postal code
1941933111

Approval date
2018-07-18, 1397/04/27

Ethics committee reference number
IR.IAU.PS.REC.1397.080

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
quality of life

Timepoint
baseline, three months after the start of intervention

Method of measurement
Questionnaire

2

Description
Symptoms

Timepoint
baseline, three months after the start of intervention

Method of measurement
Examination and diagnostic procedures

Secondary outcomes

1

Description
IgE antibody

Timepoint
baseline and three months after the start intervention

Method of measurement
elisa

2

Description
Brain and Spinal Cord Plaques

Timepoint
baseline and three months after the start of intervention

Method of measurement
MRI

3

Description

IgE antibody

Timepoint

baselines and three months after the start intervention

Method of measurement

elisa

4

Description

IgG antibody

Timepoint

baseline and three months after the start of intervention

Method of measurement

elisa

Intervention groups

1

Description

Intervention group:One milligram pill will take clemastine fumarate every 12 hours for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group:The placebo is taken every 12 hours for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Clinic of baghiyatallah hospital

Full name of responsible person

Dr.Yunes Panahi

Street address

Mollasadra street,Vanak Square

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0436

Email

Baghiyatallah@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Street address

Mollasadra street,Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8248 3253

Email

Baghiyatallah@gmail.com

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Tayyebe zamani

Position

Pharma

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Yakhchal Street, Shariati Street, Gholhak

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0051

Email

Zamanitayyebe@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Position

Ph.D of clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mollasadra street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8248 3250

Email

yunespanahi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Tayyebi zamani

Position

Pharm.D

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Mollasadra street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8248 3250

Email

Zamanitayyebi@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the information that is not personal is shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

University researchers

Under which criteria data/document could be used

Other research is to help with this disease

From where data/document is obtainable

zamanitayyebi@gmail.com

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

After sending the email up to two weeks

Comments