Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

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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 secondery 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 bind 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
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1435915371
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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
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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
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Yakhchal Street, Shariati Street, Gholhak
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Person responsible for scientific inquiries

Contact

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Bagheiat-allah University of Medical Sciences

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Position
Ph.D of clinical pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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
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
zamanitayyebe@gmail.com

What processes are involved for a request to access data/document
After sending the email up to two weeks

Comments