

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Fingolimod whit Interferon Therapy in Patients with Multiple Sclerosis

Protocol summary

Study aim

If Fingolimod is effective to the extent of Interferon in reducing of relapse and improving of disease disability ,it can be used instead of interferon

Design

Clinical trial phase 2, without control group ,sample size 30 participants

Settings and conduct

The study will be conducted on Razi and Emam Reza hospitals' patients in Tabriz

Participants/Inclusion and exclusion criteria

Relapsing Remitting multiple sclerosis,patients' age between 18 to 55 years old,disease disability score between 0 to 5.5

Intervention groups

All the patients in this study will receive Fingolimod

Main outcome variables

determining of disease disability,determining of relapse rate of disease

Country

Iran (Islamic Republic of)

Phone

+98 41 3381 0810

Email address

shaafis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Fingolimod whit Interferon Therapy in Patients with Multiple Sclerosis

Public title

Effect of Fingolimod in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age should be between 18 to 55 years old The type of disease should be Relapsing Remitting There should not be any evidence of relapse in the past 30 days EDSS score should be between 0 to 5.5

Exclusion criteria:

Have Relapse or use of Corticosteroids in the past 30 days Have an active infection Have a history of diabetes Have cardiac problems and use of anti arrhythmic drugs Taking drugs such as Azathioprine and Methotrexate WBCs less than 3500 and lymphocyte count less than

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180204038608N1**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-21, 1397/01/01**

Update count: **0**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Sheida Shaafi

Name of organization / entity

800 Taking heart beat reducer drugs

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No.2,central building,university of Medical Sciences,Golgasht ave,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

33364658

Approval date

2016-07-25, 1395/05/04

Ethics committee reference number

IR.TBZMED.REC.1395.404

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

Disease disability score,Annualized Relapse rate

Timepoint

Determining of Disease disability score at the beginning of study and after one year,Relapse rate during the past year and one year after starting Fingolimod

Method of measurement

Expanded Disability Status Scale score ,Annualized Relapse rate with negative bi nominal regression

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:capsule Fingolimod 0.5 mg daily for one year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Sona Abolhasani

Street address

Floor 3, Golgasht st, Emam Reza hospital, Tabriz, Iran

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<http://www.tbzmed.ac.ir/#>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmudpour

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research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sheida Shaafi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Sheida Shaafi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sheida Shaafi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Email

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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
main outcome report

When the data will become available and for how

long

Available from 1399

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Using of this study in other researches is admissible.

From where data/document is obtainable
Tabriz University of Medical Sciences site ,
www.Tbzmed.ac.ir ,centlibrary.tbzmed.ac.ir

What processes are involved for a request to access data/document
In order to get this document, one can refer to the university website ,or he /she can refer to the library of Tabriz university of medical sciences.

Comments