# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 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

### 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**
**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

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,centeral 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

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Neurology

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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**

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**