Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

One year comparison of effectiveness and complication of rituximab and fingolimod in multiple sclerosis (MS)patients

Protocol summary

Study aim
Comparison of the effectiveness and complication of rituximab and fingolimod in patients with Multiple Sclerosis

Design
This study is single-blinded clinical trial.The study population will be included all patients with M Multiple Sclerosis referring to Imam Reza hospital of Kermanshah. 36 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct
This study which will be conducted in Imam Reaz hospital of Kermanshah city is one-blinded one, that clinical carer will be kept blind to the allocation of study groups. At beginning of the study the motor disability and their MRI status is recorded.Patients undergo cardiac monitoring and frequent visits during rituximab and fingolimod infusion.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age between 18-55 years; Negative Pregnancy test in women of reproductive age; At least one relapse in the past year, despite First-line Dimethyltryptamine treatment; At least two relapse in the past two years, despite First-line Dimethyltryptamine treatment; Active lesions and having two or more attacks in the past year despite the first-line treatment in recurrent patients Exclusion criteria: Acute or chronic bacterial, viral or fungal infection; Breastfeeding and pregnancy; Sensitivity to drug; History of systemic diseases other than Multiple Sclerosis

Intervention groups
The first intervention group will receive 1000 mg of rituximab. The injection will take about 6 hours, the second dose will be two weeks later, and then every 6 months for one year. The second intervention group will receive 0.5 mg of fingolimod capsules, then a daily oral administration of a fingolimod capsule for a minimum of 12 months will be prescribed.

Main outcome variables
Disability motion; Medicine complications; Relapse of the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N125**
Registration date: **2019-06-07, 1398/03/17**
Registration timing: **retrospective**

Last update: **2019-06-07, 1398/03/17**
Update count: **0**

Registration date
2019-06-07, 1398/03/17

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-10, 1397/02/20

Expected recruitment end date
2019-05-10, 1398/02/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

One year comparison of effectiveness and complication of rituximab and fingolimod in multiple sclerosis (MS)patients

Public title

Comparison of effectiveness and complication of rituximab and fingolimod in improvement disability motion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-55 years Negative pregnancy test in women of reproductive age At least one relapse in the past year, despite first-line Dimethyltryptamine treatment At least two relapse in the past two years, despite First-line Dimethyltryptamine treatment Active lesions (a new Type2 (T2) or Gadolinium(GAD) enhancement) and having two or more attacks in the past year despite the first-line treatment in recurrent patients Active lesions (new T2 lesions or GAD enhancement) and attack in patients who have the progressive form of illness

Exclusion criteria:

Acute or chronic bacterial, viral or fungal infection Sensitivity to drug

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt. In this way, 36 cards which are identical in appearance will be provided and 18 of them are code 1, which specifies the intervention group, and the other are code 2, which specifies the control group.Then, anyone who is eligible to enter the study, randomly will select one of these cards(Participants will not be aware of the the type of intervention that will be assigned).

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, clinical carer will be blinded to the study groups, the dosage of the drug and the manufacturer of the drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

ir.kums.rec.1398.062

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

Disability motion

Timepoint

At the beginning of the study and one year after the study

Method of measurement

Base on Expanded Disability Scale Score(EDSS)

2

Description

Medicine complications

Timepoint

Start and during treatment

Method of measurement

Doctor observation and asking from patient

3

Description
Relapse of the disease
Timepoint
Annually
Method of measurement
Diagnosis of the doctor

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive 1000 mg of rituximab (manufactured by Takgene company) by injection. The injection will take about 6 hours, the second dose will be two weeks later, and then every 6 months for one year.
Category
Treatment - Drugs

2

Description
The second intervention group will receive 0.5 mg of fingolimod capsules(manufactured by Alhavi company). Then a daily oral administration of a fingolimod capsule for a minimum of 12 months will be prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Poona Ahmadi
Street address
Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
Resident of Neurology
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
5 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 25-day period, the documents will be sent e-mail
Comments