Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of safety and efficacy of Ziferon and Betaferon in patients with remitting -relapsing multiple sclerosis

Protocol summary

Summary

The aim of this study is to compare the safety and efficacy of Iranian interferon beta-1b (Ziferon) with its original brand (Betaferon) in the patient with relapsing-remitting multiple sclerosis. This study contains following Subordinate aims: 1-Comparison of number of relapses during of study 2-Comparison of Disability progression according to EDSS in each group 3-Comparison of MRI parameters e.g. New plaques as well progressive plaques The study will be randomized double-blind multi center Study design: The patient will be referred to the study center and will initially be examined by a neurologist or assistant of neurology. The patients will be briefed on the purpose of the study. The patients will be randomized into Ziferon or Betaferon groups after signing the generic informed consent form. Inclusion criteria: 1. Patients diagnosed with RRMS 2. Age between18-50 3. EDSS range of 0 to 5.5 4. Two relapses during the last two years. Exclusion criteria: 1-Unwanted pregnancy or decision for pregnancy during the study 2- Severe depression or psychological disorders 3- Suicide attempts 4- Sensitivity to interferon 5-Intra Venous Immuno Globuline (IVIG) infusion six months prior to study enrolment 6- Plasma exchange in the past six months 7- Injection of beta interferon in the past six months The sample size will be 76 patients and the individual patients will be studied according to the study protocol for 2 years from their enrolment date.The study was blinded by removing labels of both Ziferon and Betaferon. Therefore, all of the persons involved in the study including patient, physician and nurse except the receptionist nurse were unaware of the products.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806102397N1**

Registration date: **2015-11-13, 1394/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name

Hooshmand Ilka

Name of organization / entity

Zist Daru Danesh Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 0334

Email address

info@zistdaru.ir

Recruitment status

Recruitment complete

Funding source

Zistdaru Danesh Co.

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of safety and efficacy of Ziferon and Betaferon in patients with remitting -relapsing multiple sclerosis

Public title

Comparison of Ziferon and Betaferon in multiple sclerosis management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Patients with Remitting -Relapsing Multiple Sclerosis (RRMS) according to M.C. Donald criteria 2. Age between 18-50 years old 3. Expanded Disability Status Scale (EDSS) between 0-5.5 4. Completing informed consent 5. No relapse during last month 6. Negative pregnancy test 7. Having 2 attacks during last 2 years Exclusion Criteria 1. Pregnancy 2. Severe depression 3. History of suicide 4. Hypersensitivity to interferon beta preparations 5. Receiving IVIG (Intravenous Immunoglobulin) in the previous 6 months 6. History of plasma exchange in the last six months 7. History of interferon beta using in the previous six months 8. History of cytotoxic drug using in the previous six months 9. Impaired liver enzymes 10. Leukopenia 11. Non RRMS 12. Concomitant other autoimmune diseases 13. History of malignancy 14. Chronic liver disease except Gilbert 15. Chronic renal failure (Creatinine>1.1) 16. Claustrophobia 17. Sensitivity to Gadolinium 18. Participating in another trial 19. Nursing

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Two arms of study are prescribed randomly either Betaferon or Ziferon in equal proportion. Neither the physician nor patient is informed about prescribed medicine so both groups are blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tehran University of Medical Sciences

Street address

Faculty of Pharmacy, Tehran University of Medical Sciences. Enghelab street, Tehran-Iran

City

Tehran

Postal code

6451/14155

Approval date

2008-11-03, 1387/08/13

Ethics committee reference number

764/425

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis (MS)

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Number of Relapses.

Timepoint

Before the study and every three months after the start of the study

Method of measurement

Examining Patients

2

Description

Change in Disability

Timepoint

Before the study and every three months after the start of the study

Method of measurement

EDSS

Secondary outcomes

1

Description

Number of new plaque and plaque enhancement in each group

Timepoint

Before the study and every six months after the start of the study

Method of measurement

MRI

2

Description

Neutralizing Antibody

Timepoint

Before the study and every six months after the start of the study

Method of measurement

cytopathic effect assay (CPE)

Intervention groups

1

Description

Intervention group: Ziferon 250 micrograms produced by Zistdaru Danesh (Iran), every other day subcutaneous injection for two years.

Category

Treatment - Drugs

2

Description

Control: Betaferon 250 micrograms produced by Schering (Germany), every other day subcutaneous injection for two years.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital- Tehran

Full name of responsible person

Mohammad Reza Gheini, Neurologist,Assistant Professor

Street address

Hassan Abad Square,Sina Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Alzahra University Hospital

Full name of responsible person

Dr Masoud EtemadifarNeurologist,Professor

Street address

Isfahan Multiple Sclerosis Clinic, Al-Zahra Hospital, Soffeh Street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Vice chancellor for research, Tehran University of Science

Full name of responsible person

Dr. Pooneh Salari

Street address

6th floor,Keshavarz Blvd,Corner of Qods Ave,Vice Chancellor for Research and Technology of Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Medical Vice chancellor for research, Tehran University of Science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Zist Daru Danesh Company

Full name of responsible person

Dr. Hooshmand Ilka

Street address

NO 33, Alongside Sibouyeh Str. Ebn-e-Yamin St., North Sohrevardi Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Daru Danesh Company

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Mohammad Reza Gheini

Position
Assistant Professor of Neurology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty