

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 between 18-50 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 Relapsing -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

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Pharmacologist

**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*