Clinical Trial Protocol
Iranian Registry of Clinical Trials
11 Aug 2020

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**


**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**

Double blinded

**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
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 Etemadifar, Neurologist, 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
Person responsible for scientific 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
Sina Hospital, Hassan Abad Square

City
Tehran

Postal code
1136746911

Phone
+98 21 6634 8500

Fax
+98 21 6634 8555

Email
gheini@gmail.com

Web page address
WWW.SINAIH.COM

Person responsible for updating data

Contact

Name of organization / entity
Zist Daru Danesh

Full name of responsible person
Hooshmand Ilka

Position
Pharmacologist

Other areas of specialty/work

Street address
No.1462, North Karegar St., Pharmaceutical Incubator of Tehran University of Medical Sciences

City
Tehran

Postal code
Phone
+98 21 8835 0334

Fax
+98 21 8800 7785

Email
info@zistdaru.ir

Web page address
www.zistdaru.ir

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