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
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)**

**Blinding description**

Not used

**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 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

**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