

Evaluation of serum levels of chemokines during interferon beta treatment in multiple sclerosis patients

Submission date
02/12/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/01/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/09/2012

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Eduardo Donadi

Contact details

Avenida Bandeirantes 3900
Ribeirão Preto
Brazil
14049-900

Additional identifiers

Protocol serial number

Serum chemokines and multiple sclerosis number 1

Study information

Scientific Title

Longitudinal evaluation of serum chemokine levels in multiple sclerosis patients treated with interferon beta

Study objectives

Association of serum chemokines with age, gender, time of disease, disability, lesions on magnetic resonance, and treatment in patients with multiple sclerosis

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the Ribeirão Preto School of Medicine, University of São Paulo approved on the 22nd May 2006 (ref: 3820/2006)

Primary study design

Observational

Study design

Longitudinal observational cohort study

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Blood samples were taken 7 times each other month for one year. Clinical evaluation, EDSS score and imaging by magnetic resonance at the initial and final evaluation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Comparison of serum chemokines levels with patients and disease characteristics

Key secondary outcome(s)

Comparison of serum chemokines levels with lesions by magnetic resonance imaging (MRI)

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Patients with multiple sclerosis diagnosed by McDonald criteria 2001
2. Aged between 18 and 50 years old
3. Up to ten years of disease
4. Up to 5 points on the Expanded Disability Status Scale (EDSS)
5. At least one gadolinium enhancement lesion on magnetic resonance or one clinical relapse in the year prior to study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnancy
2. Treatment with immunosuppressor regimen
3. Stability of disease more than one year

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

Brazil

Study participating centre

Avenida Bandeirantes 3900

Ribeirão Preto

Brazil

14049-900

Sponsor information**Organisation**

Foundation to Support Education, Research and Assistance (Fundação de Apoio ao Ensino, Pesquisa e Assistência [FAEPA]) (Brazil)

Funder(s)

Funder type

Research organisation

Funder Name

Research and Teaching Support Foundation (Fundação de Amparo ao Ensino e Pesquisa e Assistência [FAEPA]) (Brazil) - Clinical Hospital, Ribeirão Preto School of Medicine, University of São Paulo

Funder Name

Bayer Schering (Brazil) - Chemokine kits were bought using funds from a unconditional grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No