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

Submission date	Recruitment status	[ ] Prospectively registered
02/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/01/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/09/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 ressonance, 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)

Study design
Longitudinal observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 ressonance at the initial and final evaluation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Comparison of serum chemokines levels with patients and disease characteristics

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

Overall study start date
01/07/2006

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 enhacement lesion on magnetic ressonance or one clinical relapse in the year prior to study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Pregnancy
2. Ttreatment with immunossupressor 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)

Sponsor details
Clinical Hospital
Ribeirão Preto School of Medicine
University of São Paulo
Avenida Bandeirantes 3900
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Sponsor type
Research organisation

Website
http://www.fmrp.usp.br

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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