A pilot multi-centre randomised controlled trial of sequential treatment with Mitoxantrone and Glatiramer Acetate vs Interferon Beta-1a in early active relapsing remitting Multiple Sclerosis

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
31/08/2012	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Mike Boggild

Contact details

The Walton Centre for Neurology and Neurosugery Lower Lane Fazakerley Liverpool United Kingdom L9 7LJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0259157815

Study information

Scientific Title

Study objectives

Does sequential treatment with Mitoxantrone and Glatiramer Acetate (Copaxone) vs Interferon Beta in early active relapsing remitting Multiple Sclerosis lead to better patient outcomes (in terms of the reduced relapses, reduced disability and improved quality of life)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nervous System Diseases: Multiple sclerosis (MS)

Interventions

Does sequential treatment with Mitoxantrone and Glatiramer Acetate (Copaxone) vs. Interferon Beta in early active relapsing remitting Multiple Sclerosis lead to better patient outcomes (in terms of the reduced relapses, reduced disability and improved quality of life)? The study design was chosen in order to have a 'head to head' comparison of this new combination versus the best available therapy. Consultation was held with lead neurologists in other regional centres. The reason for comparing this treatment combination to high-dose Interferon Beta (Rebif 44) is that in most UK centres interferon would be considered 'standard or best' management of active relapsing remitting multiple sclerosis. There was no consideration of using a placebo as not to treat this patient group would lead to sustained disability in the long term (and would be unethical). The risks to the patients are minimised by

proper safety tests (including echocardiograms, blood and urine tests) both before and during treatment. Also, the patients will not be excessively inconvenienced as we have tailored visits to be similar to what occurs in normal NHS practice.

Timetable:

- February 2005 January 2006: Recruitment of Patients
- January 2006 January 2009: Follow-up of patients with ongoing data collection.
- February 2009 June 2009: Analysis and Presentation/Publication of Data.

The interviews will take place at the Clinical Trials Unit at the Walton Centre for Neurology and Neurosurgery and similar units at the other participating regional trial centres. There will be a planned interim analysis at 18 months of the study. At the end of the study, the participants will receive a letter explaining the results found. To prevent any 'researcher bias', each participating centre will have a treating physician and an examining physician. The treating physician will recruit and treat the patients whereas the examining physician will do all baseline and follow-up examinations. The examining physician would be unaware or 'blinded' as to which treatment the patient is receiving and thus eliminating bias.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mitoxantrone and Glatiramer Acetate (Copaxone) vs Interferon Beta

Primary outcome measure

Multiple Sclerosis Impact Scale (MSIS) and Expanded Disability Status Scale (EDSS)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2005

Completion date

31/12/2010

Eligibility

Key inclusion criteria

- 1. Definite MS as determined by the McDonald criteria (Ann Neurol, July 2001) with a relapsing remitting disease course.
- 2. Aged 18 to 55.
- 3. 2 relapses in the past 2 years (this is part of the ABN guidelines to use GA and Interferon).
- 4. EDSS 0 5.5 (able to walk at least 100m without aid).
- 5. Disease duration less than 5 years from onset (if used later in the disease may not prevent progression).
- 6. At least 3 of the following: patients with three or more attacks in the first two years of

disease; motor involvement in early attacks (weakness/ataxia); incomplete recovery from early attacks (EDSS >1.5); 10 or more T2 weighted MRI brain lesions (these 4 items are markers of increased risk of early disability).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2005

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Walton Centre for Neurology and Neurosugery Liverpool

United Kingdom L9 7LJ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

The Walton Centre for Neurology and Neurosurgery NHS Trust (UK)

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