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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

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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
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Sponsor information

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Sponsor type
Government

Website
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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