ISRCTN53885363 https://doi.org/10.1186/ISRCTN53885363

The evaluation and treatment of cognitive symptoms in patients with multiple sclerosis (MS)

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
26/10/2009

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0176079579

Study information

Scientific Title

Study objectives
1. To examine the relationship between magnetic resonance imaging (MRI) indices and the severity of cognitive symptoms (e.g. poor memory and concentration)
2. To evaluate whether Rivastigmine Tartrate has a beneficial effect on the cognitive performance of patients with MS

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised placebo controlled crossover group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis (MS)

Interventions
Randomised placebo controlled, single dose, crossover trial with MRI and behavioural endpoints.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Behavioural data during performance of the functional imaging task and in the formal cognitive assessment
2. Absolute measures of signal intensity change in regions of interest in the functional scan
3. Lesion load on T1 and T2 weighted MRI scans
4. The percentage of the white matter in the patient that has T1 values greater than normal

Key secondary outcome(s)
1. Behavioural effect on other tasks within the neuropsychological battery
2. Possible side effects

Completion date
01/11/2003

Eligibility

Key inclusion criteria
12 Healthy people. 24 Patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2000

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

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	01/12/2003		Yes	No