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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2009	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
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

Study design
Randomised placebo controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
1. Behavioural effect on other tasks within the neuropsychological battery
2. Possible side effects

Overall study start date
01/11/2000

Completion date
01/11/2003

Eligibility

Key inclusion criteria
12 Healthy people. 24 Patients.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
36

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxford Radcliffe Hospitals 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2003		Yes	No