

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/10/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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