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Randomised placebo-controlled trial of intravenous methylprednisolone in relapsed multiple sclerosis patients without the need for ranitidine cover

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 18/01/2016	**Condition category** 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

N0295122823

Study information

Scientific Title
Randomised placebo-controlled trial of intravenous methylprednisolone in relapsed multiple sclerosis patients without the need for ranitidine cover

Study objectives
Is it safe to administer intravenous methylprednisolone treatment without the need for gastric-mucosal protection by ranitidine?

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)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Multiple sclerosis (MS)

Interventions
Sixty matched patients from those admitted for intravenous methylprednisolone treatment for their relapsed multiple sclerosis. Thirty will be randomised for an additional oral ranitidine cover, and the other 30 will be randomised for placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylprednisolone, ranitidine

Primary outcome measure
Between group differences in the absolute number of those who develop gastro-intestinal symptoms.

Secondary outcome measures
The number of those who develop gastro-intestinal symptoms who on clinical grounds require further investigation of their gastric mucosa for a possible ulcer or erosions in the 3, 6 and 12 months follow up durations.

Overall study start date
24/07/2003

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Sixty matched patients from those admitted for intravenous methylprednisolone treatment for their relapsed multiple sclerosis.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
24/07/2003

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Coventry
United Kingdom
CV2 2DX

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
University Hospitals Coventry and Warwickshire NHS Trust

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