

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 18/01/2016	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration