ISRCTN46231139 https://doi.org/10.1186/ISRCTN46231139

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
18/01/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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