

Randomised Double Blinded Placebo Controlled Trial of Magnesium Sulphate in Reducing Length of Hospital Stay In Patients Undergoing Elective Large Bowel Resection

Submission date 03/12/2004	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 21/02/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 16/06/2011	Condition category Digestive System	☐ 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
04/Q0102/39

Study information

Scientific Title

Acronym

Magnesium Trial

Study objectives

Not provided at time of registration

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

Large bowel resection

Interventions

Trial never started.

This study aimed to involve patients undergoing elective large bowel resection (right and left hemicolectomy, sigmoid colectomy and anterior resection) at the Ipswich Hospital for benign or malignant disease of the colon and rectum.

Patients were to have been randomised to receive either oral magnesium sulphate (1 g oral suspension, twice daily) or a placebo (oral suspension, twice daily) for 5 days. The status of the subjects, whether those taking the active substance or the group taking the placebo drug would not be known by the investigators as this was to be a double blinded study. The pharmacy would produce the inactive placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Magnesium sulphate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2006

Reason abandoned (if study stopped)

Never started.

Eligibility

Key inclusion criteria

We intend to recruit 108 subjects initially as follows:

A sample size of 54 in each group will have 90% power to detect a probability of 0.319* that an observation in Group 1 is less than an observation in Group 2 using a Wilcoxon (Mann-Whitney) rank-sum test with a 0.050 two-sided significance level.

*From a mean length of stay of 6 days in one group (Group 1) and 8 in the other group (Group 2), with a Standard Deviation of 3.000.

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

02/01/2005

Date of final enrolment

30/06/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Surgery
Ipswich
United Kingdom
IP4 5PD

Sponsor information

Organisation
Ipswich Hospital NHS Trust (UK)

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration