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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

Registration date
21/02/2005

Overall study status
Stopped

Last Edited
16/06/2011

Condition category
Digestive System

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/01/2005

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
108

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
England

United Kingdom

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

Sponsor information

Organisation
Ipswich Hospital NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital 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