

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

<b>Submission date</b> 03/12/2004	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/02/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/06/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)

**Sponsor details**

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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