ISRCTN86357226 https://doi.org/10.1186/ISRCTN86357226

# A randomised controlled trial of bismuth in the treatment of functional diarrhoea

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|---|---|---|
| **Submission date**<br>12/09/2003 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Stopped | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>27/09/2011 | **Condition category**<br>Digestive System | [ ] Individual participant data<br>[ ] 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**
N0192080637

# Study information

### Scientific Title

### Study objectives
Can treatment with bismuth salts improve symptoms in subjects with functional diarrhoea and enteroendocrine cell hyperplasia?

### 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)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Digestive System: Diarrhoea

### Interventions
1. Bismuth treatment group
2. Placebo

Added July 2008: trial never started, due to poor recruitment and lack of resources.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Symptom Score (Bowel frequency/day, days of pain/week, presence of urgency, stool consistency), enteroendocrine cell and intraepithelial lymphocyte count on rectal biopsy.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
13/09/1999

### Completion date
30/11/2004

### Reason abandoned (if study stopped)
Poor recruitment and lack of staff

## Eligibility

### Key inclusion criteria
1. Age range of subjects: patients = 18-80 years; control patients 18-80 years
2. Sex of subjects: patients = both; control patients = both

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
80 Years

### Sex
Both

### Target number of participants
15 patients with functional diarrhoea, 15 control patients, total=30.

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
13/09/1999

### Date of final enrolment
30/11/2004

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Division of Gastroenterology**
Nottingham
United Kingdom
NG7 2UH

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Government

**Funder Name**
Queen's Medical Centre University 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