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

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 27/09/2011	**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
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

Study type(s)
Not Specified

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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration