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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

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