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Barium enema: does splitting the buscopan dose reduce patient discomfort, whilst maintaining image quality?

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 26/10/2011	**Condition category** Surgery	

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

N0226127781

Study information

Scientific Title

Study objectives
To investigate if splitting the 20 mg of Buscopan (hyoscine-butylbromide) into two doses of 10 mg each, with one dose being administered at the usual point in the examination, and the second dose being administered just before the final images are obtained, will decrease patient discomfort, with no loss of image quality.

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)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Barium enema

Interventions
1. 20 mg of buscopan (hyoscine-butylbromide) at the usual point in examination
2. 20 mg of buscopan (hyoscine-butylbromide) split into two doses of 10 mg each, with one dose being administered at the usual point in the examination, and the second dose being administered just before the final images are obtained

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Barium

Primary outcome measure
Completion of examination

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
01/06/2005

Eligibility

Key inclusion criteria
200 patients attending for barium enema examination, 100 of which will be the controls

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
200

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2003

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Manchester University Hospitals NHS Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract C52, P027	01/05/2005		No	No