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Studies on the behavioural effects of fear: pilot study of the effects of inhaled carbon dioxide on subjective emotions and physiological measures in patients with irritable bowel syndrome (IBS)

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/04/2009	Digestive System	

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
N0264149443

Study information

Scientific Title

Study objectives
To explore whether traditional anxiolytic lorazepam administered orally prior to the procedure can attenuate fear and anxiety.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Irritable bowel syndrome (IBS)

Interventions
Single, blind, placebo controlled trial of inhaled carbon dioxide with traditional anxiolytic lorazepam administered orally prior to the procedure.

Intervention Type
Drug

Phase

Not Applicable

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

Primary outcome measure
Measurable fear using subjective ratings

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2004

Completion date
01/08/2005

Eligibility

Key inclusion criteria
Patients with irritable bowel syndrome (IBS)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Sample group: 12 patients with IBS and 12 healthy volunteers

Key exclusion criteria
History of cardiovascular or respiratory disease

Date of first enrolment
01/08/2004

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research & Effectiveness Department
Bristol
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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?
Results article	results	01/01/2009		Yes	No