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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 United Kingdom BS2 8HW

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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