

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 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ 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

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Measurable fear using subjective ratings

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/2005

Eligibility

Key inclusion criteria

Patients with irritable bowel syndrome (IBS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

C/O Research & Effectiveness Department

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

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