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Randomised double-blind cross-over trial of proglumide in patients with chronic pain and/or fatigue

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 03/11/2015	**Condition category** Respiratory	

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
N0084096586

Study information

Scientific Title
Randomised double-blind cross-over trial of proglumide in patients with chronic pain and/or fatigue

Study objectives
Does proglumide offer benefit to fearful chronic pain patients, and/or patients with the chronic fatigue syndrome?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
Randomised double blind cross-over design. Baseline week of symptom diaries and questionnaires. Four weeks on either proglumide or inactive preparation, then mid study questionnaires. Four weeks on crossover preparation. Final questions.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Primary end-point: less fearfulness (as measured by anxiety and activity avoidance) in the proglumide phase of the crossover trial.

Secondary outcome measures
Secondary end-points: reduced pain scores during the proglumide phase, increased fearfulness during the ascorbic acid phase in nocebo responders.

Overall study start date
01/02/2000

Completion date
01/09/2002

Eligibility

Key inclusion criteria
40

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2000

Date of final enrolment
01/09/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

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
Other

Funder Name
The North and South Bank Research and Development Consortium (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