

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
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 03/11/2015	Condition category Respiratory	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind cross-over trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/09/2002

Eligibility

Key inclusion criteria

40

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Hull Royal Infirmary

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Other

Funder Name

The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration