

A prospective, randomised, placebo-controlled, blinded trial of gabapentin in chronic groin pain following groin hernia repair

Submission date 12/09/2003	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/01/2010	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0185109366

Study information

Scientific Title

Study objectives

Patients will be randomised into two groups who present with chronic inguinodynia - gabapentin or placebo. A preliminary questionnaire will be administered and pain scores will be recorded. Patients will be supplied with either gabapentin or placebo in an increasing dose. Patients will be followed up at 4 weeks post treatment where questionnaires and pain scores will be repeated as well as perceived side effects of the treatment recorded.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised placebo-controlled blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain

Interventions

Patients will be randomised into two groups who present with chronic inguinodynia - gabapentin or placebo. A preliminary questionnaire will be administered and pain scores will be recorded. Patients will be supplied with either gabapentin or placebo in an increasing dose. Patients will be followed up at 4 weeks post treatment where questionnaires and pain scores will be repeated as well as perceived side effects of the treatment recorded.

Added 11/01/2010: trial stopped due to lack of funding

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

gabapentin

Primary outcome measure

That gabapentin, an anticonvulsant drug used in the treatment of neuropathic pain, significantly reduces pain in patients with inguinodynia.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

Completion date

31/12/2004

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Anaesthetic Department

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Plymouth Hospitals NHS Trust (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