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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 11/01/2010	**Condition category** Signs and Symptoms	

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
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