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Randomised controlled trial of intrathecal diamorphine in the treatment of chronic non-malignant pain

Submission date 12/09/2003	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 02/08/2013	**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

N0557115188

Study information

Scientific Title

Study objectives
1. Are intrathecal opioids useful in the treatment of severe chronic non-malignant pain?
2. Is therapeutic efficacy dose dependent?
3. Is gradual reduction of intrathecal opioid dose safe?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 07/04/10: Birmingham and Black Country Ethics Committee, Dudley Local Research Ethics Committee 23/2/2002, ref REC/35/02/Jun

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

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
1. Dose of diamorphine reduced every week by 20% of the preceding week's dose for 10 weeks
2. No change in dose of diamorphine for 10 weeks

Patient is blinded to the changes made by computer telemetry.

As of 04/10/2011 this trial has stopped due to an increasing number of patients leaving the study.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Analgesic consumption
2. Pain level measured using Visual Analogue Score (VAS)
3. Function measured by Oswestry Disability Score (ODS)
4. Psychological parameters measured by Hospital Anxiety & Depression Score (HAD) and 5. Pain Coping Strategies Questionnaire (PCSQ)
6. Sociological parameters measured by SF-36
7. Overall assessment of change measured by Global Impression of Change (GIC)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
31/12/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Added 07/04/10:
Intrathecal pump in situ patient at Russells Hall Hospital

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Aim to recruit 24 patients to the study.

Key exclusion criteria

Added 07/04/10:
Patients failing to give consent

Date of first enrolment
01/01/2003

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant in Pain Management
Dudley
United Kingdom
DY1 4SE

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
The Dudley Group of 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/07/2013		Yes	No