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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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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)

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
The Dudley Group of Hospitals NHS Trust (UK)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes