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Randomised double-blind placebo-controlled crossover trial of diamorphine by implantable drug delivery system in the treatment of chronic non-malignant pain

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
26/07/2013

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0557115189

Study information

Scientific Title

Study objectives
Do implanted intrathecal analgesic drug pumps relieve pain in patients with chronic non-malignant pain?

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 placebo-controlled crossover

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
1. Pump filled with diamorphine in normal saline set initially to deliver 0.5 ml/day (0.1 ml)
2. Pump filled with normal saline and set initially to deliver 0.1 ml per day

For the first 2 weeks the pump can be increased by 0.05 ml/day at half-weekly reviews if the patient describes inadequate pain relief. The pump rate will remain constant for the next 4 weeks and be returned to 0.1 ml/day by week 8 (in half-weekly intervals by increments of 0.05 ml /day). The pump is then refilled with the alternative mixture and the process repeated, ending with 0.1 ml/day by week 8 of the second pump refill (week 16).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Pain relief by Visual Analogue Scale (VAS)
2. Function by Oswestry Disability Score
3. Psychological parameters by Hospital Anxiety Depression Score
4. Pain Coping Strategies Questionnaire
5. Sociological factors by Short Form-36 Questionnaire
6. Overall Assessment by Global Impression of Change

Key secondary outcome(s)

Not provided at time of registration

Completion date
30/04/2004

Eligibility

Key inclusion criteria
Aim to recruit 16 patients to the trial from patients scheduled for intrathecal pump implantation for the delivery of diamorphine in the management of chronic non-cancer pain.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2002

Date of final enrolment
30/04/2004

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	01/07/2013		Yes	No