ISRCTN45019882 https://doi.org/10.1186/ISRCTN45019882

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

Contact name
Dr Jonathan Raphael

Contact details
Consultant in Pain Management
Guest Hospital
Tipton Road
Dudley
United Kingdom
DY1 4SE
+44 (0)1384 244809
JH.Raphael@dgoh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised double-blind placebo-controlled crossover

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
16

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
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	01/07/2013		Yes	No