

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

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/08/2013	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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