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A prospective study to compare the effectiveness of giving normal release morphine sulphate overnight on a regular 4 hourly basis or on an 'as required basis' in patients with cancer

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0258107458

Study information

Scientific Title
A prospective study to compare the effectiveness of giving normal release morphine sulphate overnight on a regular 4 hourly basis or on an 'as required basis' in patients with cancer

Study objectives
To explore the best way of administering normal release morphine overnight. To determine the difference in pain control, sleep disturbance, and patient preference between the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Cancer: Pain management

Interventions
Randomised test intervention versus standardised intervention, non-blinded (Phase 3).
Group A: On days 1 and 2, patients will be given 4 hourly morphine during the day and at 23.00 h, 03.00 h and 07.00 h at night. On days 3 and 4, patients will be given 4 hourly morphine during the day and a single dose of morphine at 23.00 h and a single 4 hourly dose at 07.00 h (ie omitting the 03.00 h dose)
Group B: On days 1 and 2, patients will be given 4 hourly morphine during the day and a single

dose of morphine at 23.00 h and a single 4 hourly dose at 07.00 h (ie omitting the 03.00 h dose). On days 3 and 4, patients will be given 4 hourly morphine during the day and at 23.00 h, 03,00 h and 07.00 h at night.
In both Groups: all patients have the option of requesting a breakthrough dose of morphine at any time, equivalent to a single 4 hourly dose.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
To provide an evidence base for overnight administration regimes for patients receiving normal release morphine for cancer pain.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
01/08/2003

Eligibility

Key inclusion criteria
Multicentre 85 patients.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
85

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2001

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
Australia

United Kingdom

Study participating centre
Mater Adult Hospital
South Brisbane
Australia
Qld 4101

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
Hospital/treatment centre

Funder Name
The Royal Marsden NHS Foundation 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