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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
To provide an evidence base for overnight administration regimes for patients receiving normal release morphine for cancer pain.

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

Completion date
01/08/2003

Eligibility

Key inclusion criteria
Multicentre 85 patients.

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
01/09/2001

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
United Kingdom

Australia

Study participating centre
Mater Adult Hospital
South Brisbane
Australia
Qld 4101

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Marsden NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration