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	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
14/02/2018	Cancer	Record updated in last year

Plain English summary of protocolNot 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

Study design

Randomised controlled trial

Primary study design

Interventional

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No
Yes