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Sublingual methadone for the management of cancer-related breakthrough pain in outpatients

Submission date 01/05/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/07/2006	**Overall study status** Stopped	
Last Edited 31/01/2019	**Condition category** Cancer	

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
NCT00351715

Secondary identifying numbers
N/A

Study information

Scientific Title
Sublingual methadone for the management of cancer-related breakthrough pain in outpatients: a phase II multicentre, open label, feasibility study

Acronym
SLM OUTPT

Study objectives
The overall hypothesis is that sublingual methadone, once optimal dose has been reached, will relieve moderate to severe breakthrough pain within five minutes in at least half of episodes evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Conjoint Health Research Ethics Board, original approval 18th May 2006; amendment approval 5th October 2006.

Study design
Open label feasibility study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer-related breakthrough pain

Interventions
Sublingual methadone

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
To demonstrate the feasibility of a novel model to assess sublingual methadone to breakthrough pain in the outpatient setting. Specific aspects of feasibility are:
1. To demonstrate the feasibility of recruitment to a study for incident pain in the outpatient setting
2. Feasibility of dose titration in the outpatient setting
3. Feasibility of filling out the pain assessments
4. Provide preliminary evidence of efficacy
5. Provide further information to document safety of the model

Secondary outcome measures
1. To develop a model of pharmacokinetic (PK) and pharmacodynamic (PD) study of breakthrough pain
2. To develop a research tool, the Breakthrough Pain Assessment Tool (BPAT)
3. To demonstrate proof of concept, with half of patients obtaining meaningful pain reduction within five minutes of administration, when given the identified optimal dose

Overall study start date
01/06/2006

Completion date
31/12/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients aged 18 years and older are eligible if they have:
1. Pain due to cancer or its treatment
2. Controlled baseline pain
3. Episodes of breakthrough pain every day that are 4/10 in severity or greater, last ten minutes or longer, and are responsive to short acting oral opioids such as morphine or hydromorphone
4. Able to hold a volume of 1.0 cc of water under the tongue for a five minute period
5. Able to provide written, informed consent
6. Able to fill out the study forms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Severe underlying respiratory disease such that the investigator is wary about the risk of respiratory failure from modest doses of opioid
2. Prior sensitivity to methadone
3. Currently taking methadone
4. Breakthrough pain that in the opinion of the investigator is likely to change within the next seven days as a result of any of the following:
4.1. Recent or imminent radiation therapy to the main site of pain
4.2. New use of chemotherapy
4.3. Use of an injectable bisphosphonate likely to alter the pain
4.4. New use of corticosteroids within the past week with a corresponding change in pain
4.5. Other interventions judged likely to alter the pain
5. Are clinically unstable or have a life expectancy of less than one month making completion of the trial unlikely

Date of first enrolment
01/06/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Canada

Study participating centre
Room 374
Calgary
Canada
T2N 4N1

Sponsor information

Organisation
Alberta Cancer Board (Canada)

Sponsor details

1220 Standard Life Building
10405 Jasper Avenue
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Sponsor type
Charity

Website
http://www.cancerboard.ab.ca/

ROR
https://ror.org/01k1b2g25

Funder(s)

Funder type
Charity

Funder Name
Alberta Cancer Board (Canada) - Competition (ref: 4640)

Funder Name
Infrastructural support by Canadian Institutes of Health Research (CIHR) grant number: PET 69772 - we received funding for Difficult Pain Problems NET Grant. The monies received were to provide infrastructural support for research or network activities across Canada.

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