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

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

ClinicalTrials.gov (NCT)
NCT00351715

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration