

Sublingual methadone for the management of cancer-related procedural pain in inpatients

Submission date 26/04/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/07/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)
NCT00351637

Protocol serial number
N/A

Study information

Scientific Title

Sublingual methadone for the management of cancer-related procedural pain in inpatients: a phase II multicentre, open label, feasibility study

Acronym

SLM INPT

Study objectives

The overall goal of this research is to evaluate the effectiveness of sublingual methadone for cancer-related breakthrough pain (onset to time of meaningful relief and the duration of the relief of breakthrough pain). The overall hypothesis is that sublingual methadone, once optimal dose has been reached, will pre-empt or relieve moderate to severe treatment-related, incident pain within five minutes in at least half of episodes evaluated.

The purpose of this phase II study is to determine the feasibility of the dose titration and assessment protocol in the inpatient population, in the clinical setting of preventing or managing breakthrough pain, before conducting an appropriately powered phase III study. Thus the primary purpose of this study is to determine the proportion of patients who are successfully titrated to an effective dose of sublingual methadone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Conjoint Health Research Ethics Board, original approval dated 18th May 2006; amendment approval granted 24th August 2006

Study design

Open label multicentre prospective trial

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

Phase II

Drug/device/biological/vaccine name(s)

Methadone

Primary outcome(s)

The primary objective of this current phase II study is to demonstrate the feasibility of a novel model to assess sublingual methadone to relieve iatrogenic, treatment-related incident breakthrough pain.

Specific aspects of feasibility are:

1. To demonstrate the feasibility of recruitment to a study for incident pain in the inpatient setting
2. Feasibility of dose titration in the inpatient setting
3. Feasibility of filling out the pain assessments
4. Provide preliminary evidence of efficacy
5. To provide further information to document safety of the model

Key secondary outcome(s)

1. To develop a model of pharmacokinetic (PK) or 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**

1. Pain due to cancer or its treatment
2. Controlled baseline pain
3. Episodes of predictable, treatment-related pain every day that are 4/10 in severity or greater, last ten minutes or longer, or episodes of breakthrough pain not related to cancer treatment, 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 two-minute period
5. Able to provide written, informed consent
6. Able to fill out the study forms, and must be an inpatient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

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. Clinically unstable or a life expectancy of less than one month making completion of the trial unlikely
5. Patients who do not have an understanding of English enough to provide written, informed consent

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