ISRCTN72738824 https://doi.org/10.1186/ISRCTN72738824

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

Submission date 26/04/2006	**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

Contact name
Dr Neil Hagen

Contact details
Room 374
Heritage Medical Research Building
3330 Hospital Dr. N.W.
Calgary
Canada
T2N 4N1
+1 403 521 3446
neilha@cancerboard.ab.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00351637

Secondary identifying numbers
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

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
Phase II

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

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/06/2006

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

Age group
Adult

Sex
Both

Target number of participants
20

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)

Sponsor details
1220 Standard Life Building
10405 Jasper Avenue
Calgary
Canada
T5J 3N4
+1 403 521 3446
neilha@cancerboard.ab.ca

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