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Study of PRC-062 in patients with chronic non-cancer pain

Submission date	Recruitment status	[ ] Prospectively registered
11/11/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/12/2013	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to see if a drug called PRC-062 works as well as the drug named CR hydromorphone in treating chronic non-cancer pain.

Who can participate?
Adults taking CR hydromorphone for the treatment of chronic non-cancer pain for at least 3 months can participate in this study.

What does the study involve?
The study has two phases. In the first phase all participants will receive CR hydromorphone. In the second phase participants will be randomly allocated to receive either CR hydromorphone or PRC-062. They will be followed up at their clinic visits.

What are the possible benefits and risks of participating?
Participation in this study will provide important information on the safety and effectiveness of PRC-062, which may benefit other patients with chronic pain. The main risks are expected to be similar to those associated with the regular use of CR hydromorphone.

Where is the study run from?
The study is run in clinics located in Canada.

When is the study starting and how long is it expected to run for?
The study started in November 2013 and is expected to run for approximately one year.

Who is funding the study?
Purdue Pharma, Canada.

Who is the main contact?
Purdue Pharma Product Information
productinfo@purdue.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
062-010

Study information

Scientific Title
Phase III, randomized, double-blind, active-controlled, parallel arm study of PRC-062 in patients with chronic non-cancer pain

Study objectives
PRC-062 at equal doses is as effective as CR hydromorphone in maintaining pain control in subjects with stable chronic non-cancer pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) Services, Aurora, Ontario, Canada, 11/09/2013

Study design
Multicenter randomized double-blind active-controlled parallel arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Interested patients may have their family physician use the contact details below to request information on the study.

Health condition(s) or problem(s) studied
Chronic non-cancer pain

Interventions
The duration of the study is six weeks. In the first phase all subjects will receive CR hydromorphone. In the second phase, subjects will be randomized to receive either CR hydromorphone or PRC-062 and will be followed-up at weekly clinic visits.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
PRC-062, CR hydromorphone

Primary outcome measure
Proportion of subjects in each arm who require a dose change from their pre-randomization CR hydromorphone dose, irrespective of when during the post-randomization period this dose change occurs

Secondary outcome measures
1. Magnitude of the mean dose change between treatment arms
2. Within-subject magnitude of the dose change from pre- to post-randomization
3. Rescue medication usage
4. Pain Intensity Questionnaire (PIQ), at weekly visits during the study
5. Beck Depression Inventory (BDI), at weekly visits during the study
6. Pain and Sleep Questionnaire 3 Item Index (PSQ-3), at weekly visits during the study
7. Pain and Disability Index (PDI), at weekly visits during the study
8. Treatment effectiveness and satisfaction, at weekly visits during the study
9. Global Impression of Change (GIC) scale, at weekly visits during the study
10. Subjective Opiate Withdrawal Scale (SOWS), at weekly visits during the study
11. Quality of life (SF-12) questionnaire, at weekly visits during the study
12. Brief Pain Inventory (BPI), at weekly visits during the study
13. Bowel Function Index (BFI), at weekly visits during the study
14. Laxative use

The secondary endpoints of magnitude of the mean dose change between treatment arms, the within-subject magnitude of the dose change from pre- to post-randomization, laxative use and rescue medication use will be captured irrespective of when during the post-randomization period these changes occur.

The mean change from baseline in all endpoints will be measured.

Overall study start date
01/11/2013

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Male or non-pregnant, non-nursing female subjects of 18 years of age or older
2. History of chronic non-cancer pain for six months or more
3. Subjects who at time of screening require stable doses of CR hydromorphone not exceeding 60 mg per day for a period of three months or more prior to entry into the study and who report satisfaction with their pain management

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Subjects who do not respond adequately to on-label dosing of CR hydromorphone at doses not exceeding 60 mg per day
2. Subjects with cancer
3. Inhaled cannabis use
4. Compromised kidney or liver function
5. Conditions that may adversely affect safety or obscure the assessment of efficacy
6. Risk for central nervous system (CNS) or respiratory depression
7. Significant gastrointestinal (GI) structural abnormalities or diseases/conditions that may affect bowel function
8. Major psychiatric disorder
9. Received an investigational drug in the past month
10. Taking monoamine oxidase (MAO) inhibitors

Date of first enrolment
01/11/2013

Date of final enrolment

31/07/2014

Locations

Countries of recruitment
Canada

Study participating centre
575 Granite Court
Pickering, Ontario
Canada
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Sponsor information

Organisation
Purdue Pharma (Canada)

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Sponsor type
Industry

ROR
https://ror.org/023sxys58

Funder(s)

Funder type
Industry

Funder Name
Purdue Pharma (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