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A randomised, crossover study of study drug 038 and controlled-release oxycodone HCl tablets in patients with chronic non-cancer pain

Submission date 09/12/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/01/2009	**Overall study status** Completed	
Last Edited 10/01/2011	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
038-002

Study information

Scientific Title

Study objectives
Study drug 038 will be superior to controlled-release (CR) oxycodone on bowel function and not inferior to CR oxycodone in pain control in patients with chronic non-cancer pain.

As of 13/08/2010 this record was updated to include an extended end date; the initial anticipated end date at the time of registration was 15/09/2009.

As of 10/01/2011 this record was again updated to include an extended end date; the previous anticipated end date at the time of registration was 31/03/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lead centre received approval from IRB Services, Aurora, Ontario (Canada) on 10 June 2008

Study design
Multicentre randomised double-blind crossover trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Oral opioid analgesic (038) titrated to effect over a five-week phase with matched CR oxycodone arm.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Study drug 038, controlled-release oxycodone HCl

Primary outcome(s)
Pain intensity and bowel function measured during the last week of treatment in each phase.

Key secondary outcome(s))
All assessments measured during the last week of treatment in each phase:
1. ROME-III
2. Patient Assessment of Constipation Symptoms (PAC-SYM)
3. Brief Pain Inventory
4. Multidimensional Pain Inventory

5. Beck Depression Inventory
6. Pain Disability Index
7. Pain and Sleep Questionnaire
8. Level of Activity

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Male or non-pregnant, non-nursing female patients over the age of 18 years with chronic non-cancer pain of moderate or greater intensity for at least three months
2. Patients who require stable doses of 60 to 80 mg every 12 hours of oxycodone or its analgesic equivalent
3. Patients experiencing less than three complete, spontaneous bowel movements in the seven days prior to randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who undergoing any treatments that may change their pain during the study, such as physiotherapy, corticosteroid injections or surgical procedures
2. Patients who do not respond adequately to doses of 60 or 80 mg every 12 hours of oxycodone
3. Patients whose pain is expected to be refractory to continuous opioid therapy
4. Patients with allergy to study drug 038, oxycodone or any other opioid
5. Patients with any of the following:
5.1. A condition that affects patient safety or obscures the assessment of efficacy
5.2. Compromised kidney or liver function
5.3. Risk for central nervous system (CNS) and/or respiratory depression
5.4. Significant gastrointestinal structural abnormalities or diseases/conditions that affect bowel function
5.5. A major psychiatric disorder
5.6. Received an investigational drug in the last month
5.7. Failed the urine drug screen

Date of first enrolment

31/07/2008

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Canada

Study participating centre
Purdue Pharma
Pickering, Ontario
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Sponsor information

Organisation
Purdue Pharma Canada

ROR
https://ror.org/023sxys58

Funder(s)

Funder type
Industry

Funder Name
Purdue Pharma Canada (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes