

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

<b>Submission date</b> 09/12/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/01/2011	<b>Condition category</b> Signs and Symptoms	<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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format. Please have your family physician use the contact details below to request information on the study.

### 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 measure**

Pain intensity and bowel function measured during the last week of treatment in each phase.

**Secondary outcome measures**

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

**Overall study start date**

31/07/2008

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

## **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

### **Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://www.purdue.ca>

**ROR**

<https://ror.org/023sxys58>

**Funder(s)****Funder type**

Industry

**Funder Name**

Purdue Pharma Canada (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