

A randomised, placebo-controlled, titration-to-effect, crossover study of study drug 038 in patients with chronic low back pain

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
12/06/2008	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
04/07/2008	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
13/08/2010	Musculoskeletal Diseases	<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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Pickering
Canada
L1W 3W8

Additional identifiers

Protocol serial number

038-001

Study information

Scientific Title

Study objectives

Study drug 038 will be superior to placebo on the treatment of chronic low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval for the lead centre was received from IRB Services, Aurora, Ontario (Canada) on December 1, 2006. All other participating centres obtained ethics approval before recruiting study participants.

Study design

Multi-centred, randomised, double-blind, placebo-controlled crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic low back pain

Interventions

Oral opioid analgesic (038) titrated to effect over a four-week phase with matched placebo arm.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Study drug 038

Primary outcome(s)

Pain intensity 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. Quebec Back Pain
2. Pain and sleep
3. Pain and disability
4. Quality of life
5. Bowel function

Completion date

30/04/2008

Eligibility

Key inclusion criteria

1. Male or non-pregnant females at least 18 years of age
2. Chronic low back pain of at least moderate intensity for at least three months
3. Patients who require opioids to control their pain

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients who may require more than 12 tablets of Tylenol No. 3 per day
2. Patients whose pain is expected to be refractory to opioid therapy
3. Patients with intolerance to study drug 038, acetaminophen or any other opioid
4. Patients with significant sources of unrelated pain that may obscure the assessment of efficacy
5. Patients with any of the following medical conditions:
 - 5.1. Risk for central nervous system (CNS) and/or respiratory depression
 - 5.3. Active inflammatory gastrointestinal disease
 - 5.4. Peptic ulcer disease
 - 5.5. Major psychiatric disorder
 - 5.6. Any condition that may obscure patient safety or efficacy assessment
 - 5.7. Patients who have received an investigational drug within the last month

Date of first enrolment

01/12/2006

Date of final enrolment

30/04/2008

Locations

Countries of recruitment

Canada

Study participating centre

Purdue Pharma
Pickering
Canada
L1W 3W8

Sponsor information

Organisation

Purdue Pharma Canada

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Purdue Pharma 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