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

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	☐ Results
Condition category	Individual participant data
Musculoskeletal Diseases	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paula Piraino

Contact details

Purdue Pharma 575 Granite Court Pickering Canada L1W 3W8

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 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 measure

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

Overall study start date

01/12/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Patients who may require more than 12 tables 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 recruitmentCanada

Study participating centre
Purdue Pharma
Pickering
Canada
L1W 3W8

Sponsor information

Organisation

Purdue Pharma Canada

Sponsor details

c/o Dr. John Eisenhoffer 575 Granite Court Pickering Canada L1W 3W8 +1 905 420 6400 medinfo@purdue.ca

Sponsor type

Industry

Website

http://www.purdue.ca

ROR

https://ror.org/023sxys58

Funder(s)

Funder type Industry

Funder NamePurdue Pharma Canada

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration