ISRCTN35931095 https://doi.org/10.1186/ISRCTN35931095

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

Submission date
12/06/2008

Recruitment status
No longer recruiting

Registration date
04/07/2008

Overall study status
Completed

Last Edited
13/08/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

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.

Primary study design
Interventional

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

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 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 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