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

Registration date
04/07/2008

Last Edited
13/08/2010

Recruitment status
No longer recruiting

Overall study status
Completed

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
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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 recruitment
Canada

Study participating centre
Purdue Pharma
Pickering
Canada
L1W 3W8

Sponsor information

Organisation
Purdue Pharma Canada

Sponsor details
c/o Dr. John Eisenhoffer
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medinfo@purdue.ca

Sponsor type
Industry

Website
http://www.purdue.ca

ROR
https://ror.org/023sxys58

Funder(s)

Funder type
Industry

Funder Name
Purdue Pharma 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