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Study drug 020 versus placebo with acetaminophen rescue in patients with chronic low back pain

Submission date
25/03/2008

Recruitment status
No longer recruiting

Registration date
04/07/2008

Overall study status
Completed

Last Edited
06/08/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John Eisenhoffer

Contact details
Purdue Pharma
575 Granite Court
Pickering, Ontario
Canada
L1W 3W8
+1 905 420 6400
medinfo@purdue.ca

Additional identifiers

Protocol serial number
020-007

Study information

Scientific Title

Study objectives
Study drug 020 will be superior to placebo in 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 the Mount Sinai Hospital Research Ethics Board (REB), Toronto, ON (Canada) on 3rd August 2004. 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
Transdermal opioid analgesic (020) titrated to effect over a four-week phase with matched placebo arm, with acetaminophen rescue (325 - 650 mg every four to six hours as and when needed [q4 - 6h prn]) provided in both arms.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Study drug 020 (buprenorphine transdermal system), acetaminophen

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. Pain and disability
2. Pain and sleep
3. Quality of life
4. Functional disability

Completion date
03/03/2006

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 have not responded adequately to non-opioid analgesics and are currently taking a minimum of one tablet per day of an opioid analgesic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients with intolerance to study drug 020, acetaminophen or any opioid
2. Patients expected to require more than 12 tablets of Tylenol no. 3 per day
3. Patients whose pain is expected to be refractory to opioid therapy
4. Patients who require therapy involving direct external heat sources
5. Patients with a significant source of unrelated pain that may obscure the assessment of efficacy
6. Patients with any of the following medical conditions:
6.1. Renal or hepatic impairment
6.2. Risk of respiratory depression
6.3. Peptic ulcer disease
6.4. Active inflammatory gastrointestinal disease
6.5. Major psychiatric disorder
6.6. Congenital Long QT syndrome, or any family member with this condition
6.7. History of congestive heart failure, atrial fibrillation, myocardial ischaemia, tachycardia (greater than 100 bpm at rest) or bradycardia (less than 45 bmp at rest)
6.8. Decreased serum magnesium or potassium
6.9. Any condition that would obscure patient safety or efficacy assessment
7. Patients currently receiving any of the following:
7.1. Class IA anti-arrhythmic medications (e.g., quinidine, procainamide, disopyramide)
7.2. Class III anti-arrhythmic medications (e.g., sotalol, amiodarone)
7.3. Any medication known to cause torsades de pointes
8. Patients who received an investigational drug within the past month

Date of first enrolment
05/07/2004

Date of final enrolment
03/03/2006

Locations

Countries of recruitment
Canada

Study participating centre
Purdue Pharma
Pickering, Ontario
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?

Results article	results	01/05/2010	Yes	No