

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	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/08/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 bpm 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