

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

<b>Submission date</b> 25/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/08/2010	<b>Condition category</b> 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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

## Study design

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

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

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

**Overall study start date**

05/07/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

**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

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## **Sponsor information**

**Organisation**

Purdue Pharma (Canada)

**Sponsor details**

575 Granite Court

Pickering, Ontario

Canada

L1W 3W8

**Sponsor type**

Industry

**Website**

<http://www.purdue.ca/main/>

**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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2010		Yes	No