ISRCTN06013881 https://doi.org/10.1186/ISRCTN06013881

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

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 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)

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?
Results article	results	01/05/2010		Yes	No