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A randomised, double-blind, crossover comparison of the efficacy and safety of study drug 017 and placebo in patients with neuropathic pain due to diabetic neuropathy (DN) or post-herpetic neuralgia (PHN)

Submission date
25/03/2008

Recruitment status
No longer recruiting

Registration date
04/07/2008

Overall study status
Completed

Last Edited
04/07/2008

Condition category
Nervous System 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
017-010

Study information

Scientific Title

Study objectives
Study drug 017 will be superior to placebo in the treatment of chronic neuropathic pain due to diabetic neuropathy (DN) or post-herpetic neuralgia (PHN).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval for the lead centre was received from Institutional Review Board (IRB) Services, Aurora, ON (Canada) on 11 January 2008. 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
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
Neuropathic pain

Interventions
Centrally-acting oral opioid anlagesic (017) titrated to effect over a 4-week phase with matched placebo arm.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Study drug 017 (a centrally acting opioid analgesic)

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. Neuropathic Pain Scale
2. Pain and sleep
3. Pain and disability
4. Quality of life
5. Depression inventory

Overall study start date
21/01/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
For diabetic neuropathy patients:
1. Stable glycaemic control
2. Patients with pain in the lower extremities on a daily basis and one or more signs or symptoms of peripheral neuropathy not attributable to any other cause
3. Patients with absent or decreased ankle reflexes and loss of perception of 128 Hz vibration of the great toe

For post-herpetic neuralgia patients:
1. Primary diagnosis of PHN defined by pain for at least three months after healing of a herpes zoster skin rash

For all patients:
1. Male or non-pregnant females at least 18 years of age
2. Patients who answer yes to at least four items on the the neuropathic pain diagnostic questionnaire (DN4)
3. Patients whose pain has been of moderate intensity on most days for at least three months
4. Patients who have required the use of analgesic medication for at least three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Patients who do not have stable glycaemic control (HbA1c greater than 2 x normal) or whose anti-diabetic therapy is likely to require adjustment during the study
2. Patients with peripheral neuropathy attributable to other causes
3. Significant pain of other origin that may obscure the assessment of efficacy
4. Patients whose opioid requirement may exceed eight tablets of acetaminophen plus codeine (300/30 mg) or analgesic equivalent per day
5. Patients with true allergy to acetaminophen or any opioid, sufficient that therapy is contraindicated
6. Patients with any of the following medical conditions:
6.1. Active, severe psychiatric disorder, including severe depression
6.2. Postural hypotension
6.3. Clinically significant hepatic dysfunction (aspartate aminotransferase [AST], alanine aminotransferase [ALT], alkaline phosphatase [Alk Phos] greater than 2 x normal)
6.4. Symptomatic coronary artery peripheral vascular disease
6.5. Intermittent claudication
6.6. Brittle diabetes
6.7. Low serum cobalamin (vitamin B12)
6.8. Abnormal serum folic acid levels
6.9. Colostomy, ileostomy or shortened gastrointestinal (GI) transit time
6.10. Active or recent peptic ulcer or gastrointestinal (GI) inflammatory disease
6.11. Epilepsy, history of seizures or recognised risk for seizure
6.12. Any condition that may adversely affect patient safety or obscure assessment of efficacy
7. Patients receiving any of the following medications:
7.1. Monoamine oxidase inhibitors
7.2. Carbamazepine
7.3. Quinidine
7.4. Selective serotonin reuptake inhibitors
7.5. Serotonin norepinephrine reuptake inhibitors
7.6. Neuroleptics
7.7. Warfarin
7.8. Digoxin
8. Patients who have received an investigational drug within the previous month
9. Patients with a known or suspected history of drug or alcohol abuse

Date of first enrolment
21/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Canada

Study participating centre
Purdue Pharma
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Sponsor information

Organisation
Purdue Pharma Canada

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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