Translational trial to explore the pharmacodynamic effects of multiple oral dose administrations of tapentadol PR, pregabalin, and combinations of both in an intradermal capsaicin hypersensitization model in healthy subjects.

Published: 02-09-2015
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42611

Source
ToetsingOnline

Brief title
Pharmacodynamic study with tapentadol PR and pregabalin

Condition

- Other condition

Synonym

Neuropathic pain, Pain due to nerve damage

Health condition

neuropathische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Grunenthal
Source(s) of monetary or material Support: pharmaceutische industrie

Intervention

Keyword: capsaicin, Pregabalin, Tapentadol

Outcome measures

Primary outcome

* pain scores (on a 0 to 100 NRS) after an intradermal capsaicin injection

* Area (in cm2) of secondary mechanical hyperalgesia after intradermal

capsaicin injection

* Area (in cm2) of vascular flare after an intradermal capsaicin injection

Secondary outcome

* Average cutaneous blood flow (quantified in arbitrary units) after an

intradermal capsaicin injection.

* Mean pain intensity (0 to 100 VAS) during a 2-minute cold pressor test.

* Safety and tolerability of the drug combinations.

Study description

Background summary

Tapentadol and pregabalin are approved drugs for the treatment of neuropathic pain and are typically administered as separate treatments. It is expected that when these drugs are given together in 1 formulation (in 1 capsule, for example), lower doses of both drugs may be needed to obtain the same clinical efficacy but then with less side effects for the patients.

Study objective

The purpose of the study is to investigate the optimal dose combination of both drugs in healthy volunteers who will undergo a pain test.

Study design

The study will be performed in 2 parts, Parts A and B. Part A will consist of 2 groups of 18 male subjects each and Part B will consist of 2 groups of 24 healthy male subjects each.

For all groups, there will be 3 treatment periods in which the study drug is administered on 3 consecutive days. On Days 1 and 2, the study drug is administered twice in the morning (2 hours apart) and twice in the evening (2 hours apart). On Day 3, the study drug is administered twice in the morning only (2 hours apart). The pain tests will be performed after the last dose on Day 3 of each period.

Intervention

Tapentadol (Palexia Retard)
Pregabalin (Lyrica)
Capsaicin

Study burden and risks

Both tapentadol and pregabalin have been marketed for many years. The adverse effect profiles of both drugs are well-known, and the drugs will be administered in this study at doses that are known to be well tolerated. The most common adverse effects (more than 10% of the people) with tapentadol are nausea, constipation, dizziness, drowsiness, and headache; and with pregabalin these are are dizziness, somnolence, peripheral edema, ataxia, fatigue, xerostomia, weight gain, tremor, blurred vision, and diplopia. When the 2 drugs are combined, the chance of adverse effects occurring may increase. You should be aware that the aforementioned adverse effects and possibly other, still

unknown adverse effects, may occur during the study. However, with the doses used in this study no serious adverse effects are expected.

Capsaicin, the *hot* substance in chili peppers, is commonly used in experimental pain models in healthy volunteers and is generally regarded as safe. Administration of capsaicin gives a transient, intense pain at the site of injection, which is often described as intense burning, aching or stinging. Shortly after the injection an area of sensitization develops with allodynia (a painful response to a usually non-painful stimulus) and hyperalgesia (an increased pain sensation to mildly painful stimuli) around the injection site. In addition, there will be redness of the skin. The painfulness and redness is only short lasting and will disappear within 2 hours. The sensitization symptoms may last up to 12 to 24 hours.

The cold pain assessment as used in this study has been used extensively in studies with healthy volunteers. Even though it is painful, it is generally well-tolerated and of sufficiently short duration to avoid any risk to the health or well-being of healthy volunteers.

Contacts

Public
Grunenthal

Zieglerstrasse 6
Aachen 52078
DE
Scientific
Grunenthal

Zieglerstrasse 6
Aachen 52078
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male subjects
- 18-55 yrs, inclusive
- BMI: 20.0-30.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood (for men) / 1.0 liters of blood (for women) in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2015
Enrollment:	84
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lyrica
Generic name:	pregabalin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Palexia Retard
Generic name:	Tapentadol PR
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-09-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015□002424□39-NL
CCMO	NL54595.056.15