An Open-Label, Sequential Treatment Study to Assess the Single- and Multiple-Dose Pharmacokinetics of a New Tapentadol Prolonged-Release 250 mg Formulation in Healthy Subjects.

Published: 08-09-2008
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32556

Source
ToetsingOnline

Brief title
Open-label sequential treatment study with tapentadol.

Condition

- Other condition

Synonym
acute pain / chronic pain

Health condition

acute en chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag International N.V.
Source(s) of monetary or material Support: Janssen-Cilag International N.V.

Intervention

Keyword: open-label, pain, pharmacokinethics, tapentadol

Outcome measures

Primary outcome

Compare how the body processes single and multiple doses of tapentadol for a certain period after taking the tablets. This way absorption, excretion and distribution of the drug in the body is assessed.

Secondary outcome

Findings of the safety and tolerability.

Study description

Background summary

This study, R331333/PAI1036, tests a 250 mg tablet of tapentadol (also known as CG5503 base) Tamper Resistant Prolonged-release Formulation (called TRF) as well as a single dose and a as a multiple dose in the same study. The purpose of this study is to compare how the body handles the medicine over a period of time (called Pharmacokinetics or PK) after the intake of the tablets between a single dose and multiple doses of TRF and includes how the body absorbs, distributes and eliminates medication. In addition safety and tolerability will be assessed. Tapentadol belongs to the narcotic drugs. Tapentadol, is an experimental drug that is being developed as an painkiller (= analgesic) for the use in acute pain (such as postoperative pain) and in chronic pain (such as low back pain and arthritis (joint pain).

Study objective

The objectives are:

1. Compare how the body processes single and multiple doses of tapentadol for a certain period after taking the tablets. This way absorption, excretion and distribution of the drug in the body is assessed.

2. Findings of the safety and tolerability.

Study design

While staying in the clinical research unit for 9 days, the study will consist of 2 parts.
In the 1st part of the study, the subjects will receive one tablet (CG5503 base) of 250 mg TRF once.
In the 2nd part of the study, the subjects will receive a multiple dose (5 doses in total, every 12 hours) of tapentadol (CG5503 base) TRF of 250 mg.
The subjects will be in the study for approximately 4 weeks, including screening period.
During the study, the subjects are admitted at the clinical research unit in the evening, at least 10 hours prior to drug administration, this is on Day -1.
The subjects will stay at the clinical research unit Day 8 and may leave the unit after collection of the last PK collection on Day 8.

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of tapentadol. The burden on the volunteer will continue to work with the recording periods, venapunctions and the introduction of the cannula. All volunteers are closely monitored and supervised by experienced doctors and studystaff for possible side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Man or woman, 18 to 55 years of age, inclusive.
2. Signed informed consent.
3. Healthy on the basis of prestudy physical examination, medical history, 12-lead ECG, vital signs, and clinical laboratory parameters.
4. Received a thorough explanation of the optional pharmacogenomic research component of the study and was offered the opportunity to participate by signing the separate pharmacogenomic informed consent document.
5. Women must be postmenopausal, surgically sterile or be practicing an effective method of birth control.
6. Women must have a negative serum ß-human chorionic gonadotropin (ß-hCG) pregnancy test at screening.
7. Body mass index between 20 and 28 kg/m2 inclusive and body weight nog less than 50kg.
8. Blood pressure between 100 and 140 mmHg systolic, inclusive, and between 50 and 90 mmHg diastolic, inclusive.
9. Habitually smokes no more than 10 cigarettes, or 2 cigars, or 2 pipes of tobacco per day for at least 6 months before first study drug administration.

Exclusion criteria

1. History of seizure disorder or epilepsy or traumatic brain injury.
2. History of gastrointestinal disease affecting absorption, gastric surgery or history of or current significant medical illness including (but not limited to) cardiac arrhythmias or other cardiac disease, hematologic disease, coagulation disorders (including any abnormal bleeding or blood dyscrasias), lipid abnormalities, significant pulmonary disease (including

bronchospastic respiratory disease), diabetes mellitus, renal or hepatic insufficiency, thyroid disease, neurologic or psychiatric disease, infection, or any other illness that the investigator considers should exclude the subject.
3. History of allergies.
4. History of drug or alcohol abuse.
5. Positive test for drug or alcohol abuse.
6. Donated blood, blood products or loss of blood (> 500 mL) within 2 months before the first administration of study drug.
7. Received an experimental drug or used an experimental medical device within 30 days or within a period less than 10 times the drug's half life before the first dose of the study drug is scheduled.
8. Women who plan to become pregnant during the study, or who are breast-feeding.
9. Men and women with abnormal hemoglobin concentrations.
10. Subjects who have used prescription medications and/or over-the-counter medication (incl. ibuprofen or herbal medication) within 14 days before first study drug administration, MAOI's and SNRIs within 21 days before first study drug administration, alcohol/grapefruit juice/quinine-containing drinks/seville orange products whithin 24 hours before first study drug administration, methylxanthine-containing products within 48 hours before first study drug administration.
11. Unable to swallow solid, oral dosage forms whole with the aid of water(participants may not chew, divide, dissolve, or crush the study drug).
12. Positive test for HIV and Hepatitis.
13. Preplanned surgery or procedures that would interfere with the conduct of the study.
14. Known or suspected inability to comply with the study protocol.
15. Inability to communicate meaningfully with investigator and staff.
16. Employee of the investigator or study center, as well as family member of the employees or investigator.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-09-2008
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	tapentadol
Generic name:	tapentadol

Ethics review

Approved WMO Date:	08-09-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-09-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2008-004700-31-NL
CCMO	NL24498.040.08