An open label, crossover study to investigate the safety and tolerability of Sifrol® (pramipexole) (Boehringer Ingelheim) prolonged release tablets in order to establish the maximum tolerable dose and to assess bioequivalence of Pramipexole prolonged release tablets (Synthon B.V.) compared to Sifrol® prolonged release tablets (Boehringer Ingelheim) in healthy subjects in steady-state conditions

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To determine the relative bioavailability of pramipexole 4.5 mg tablets vs. 4.5 mg Sifrol in healthy subjects after up-titration.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON36833

Source
ToetsingOnline

Brief title
CT.PAL.mrt.45.12.001

Condition

- Structural brain disorders

Synonym
parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Synthon B.V
Source(s) of monetary or material Support: Synthon B.V.

Intervention

Keyword: bioequivalence, healthy subjects, maximum tolerability, safety

Outcome measures

Primary outcome

safety, tolerability and bioequivalence

Secondary outcome

n.a.p

Study description

Background summary

The research medication is a medication under development for treatment of the signs and symptoms of idiopathic Parkinson*s disease.

Study objective

To determine the relative bioavailability of pramipexole 4.5 mg tablets vs. 4.5 mg Sifrol in healthy subjects after up-titration.

Study design

This is an open-label, 2-period crossover study.

Intervention

The study will start with a screening At the screening a physical examination will take place and a few other standard medical assessments will be performed (Vital Signs). Furthermore a blood and urine sample will be taken for laboratory tests and a pregnancy test and drug screen will be done. During the stay in the clinic the subject will receive the study medication and on several time points blood and urine will be taken. The subjects will be asked for possible side effects on a regular basis. Furthermore several safety assessments will be done frequently.

Finally a follow up visit will take place.

Study burden and risks

Pramipexole is a registered drug (trade name: Sifrol®) that is well tolerated. However, as with any medicine, it is possible that pramipexole can cause side effects. Several clinical studies were conducted with patients with Parkinson's Disease and patients with Restless Legg Syndrome. The following adverse reactions are expected under the use of SIFROL: abnormal dreams, loss of memory, behavioural symptoms of impulse control disorders and compulsions such as binge eating (frequently eating abnormal quantities of food), compulsive shopping, hypersexuality and pathological gambling; cardiac failure, confusion, constipation, delusion, dizziness, presence of involuntary movements (dyskinesia), difficult or laborated breathing (dyspnea), fatigue, hallucinations, headache, hiccups, increased muscular movements (hyperkinesia), hyperphagia, hypotension, insomnia, libido disorders, nausea, paranoia, peripheral oedema, lung infection (pneumonia), pruritus, rash and other hypersensitivity; restlessness, somnolence, sudden onset of sleep, fainting (syncope), visual impairment including double vision (diplopia), vision blurred and visual acuity reduced, vomiting, weight decrease including decreased appetite, weight increase.

The research medication Premixole (Synthon B.V.) is not a registered drug. Nevertheless, Premixole (Synthon B.V.) is expected to be similar to Sifrol, since the active substance of both drugs is pramixole.

Furthermore, to reduce risk only subjects that are caucasian will be included in the study and each subject will receive the concomitant medication domperidone (10 mg Motilium®) three times a day against orthostatic hypotension and nausea.

The blood collection may cause discomfort and bruising. Occasionally, fainting, an infection at the blood sampling site, bleeding and blood clot formation can

occur.

Contacts

Public
Synthon B.V

Microweg 22
Nijmegen 6545 CM
NL
Scientific
Synthon B.V

Microweg 22
Nijmegen 6545 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Healthy, non-smoking, non-vegetarian, Caucasian male volunteers, 18 - 55 years of age, inclusive.;2. Body Mass Index (BMI) that is within 18.5-30.0 kg/m², inclusive.;3. Healthy, according to the medical history, ECG, vital signs, laboratory results and physical examination as determined by Principal Investigator/Sub-Investigator.;4. Supine blood pressure between 90-150 mm Hg, inclusive, systolic and 50-90 mm Hg, inclusive, diastolic and heart rate between 50-100 bpm, inclusive, unless deemed otherwise by the Principal Investigator/Sub-Investigator. ;Refer to protocol for a complete list of the inclusion criteria.

Exclusion criteria

1. Known history or presence of any medical conditon determined as clinically significant by Principal Investigator/Sub-Investigator.;2. Out of range creatinine clearance in plasma according to Cockroft and Gault.;3. Known history or presence of drug or alcohol abuse, any relevant history of sleep disorder, food allergies ;Refer to protocol for a complete list of the inclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2012
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Pramipexole (Synthon B.V.)
Generic name:	Pramipexole
Product type:	Medicine
Brand name:	Sifrol
Generic name:	Pramipexole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-08-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-08-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-08-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-11-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-11-2012
Application type:	Amendment
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	EUCTR2012-003235-36-NL
CCMO	NL41596.056.12