A Phase 1, open-label, randomized, 2-period crossover drug interaction study in healthy adult subjects to evaluate the effect of the Proton Pump Inhibitor Omeprazole on the pharmacokinetics of SSP-002358.

Published: 01-08-2011
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Primary:to examine the effect of co-administration with omeprazole on the pharmacokinetics of SSP-002358.Secondary:to provide additional safety information for SSP-002358 when administered alone or in combination with omeprazole.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON35226

Source
ToetsingOnline

Brief title
SSP-002358/omeprazole DDI study.

Condition

- Gastrointestinal conditions NEC

Synonym
gastroesophageal reflux disease

Research involving

Human

Sponsors and support

Primary sponsor: Shire-Movetis NV
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: gastroesophageal reflux disease, Omeprazole, SSP-002358

Outcome measures

Primary outcome

Criteria for evaluation

Pharmacokinetics: pharmacokinetic parameters for SSP-002358

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination

Secondary outcome

Not applicable.

Study description

Background summary

The purpose of the study is to evaluate if there is a change in the pharmacokinetics (the way the body absorbs, distributes, breaks down and eliminates medication) when SSP-002358 is taken alone and with another medication, omeprazole. In addition, the study will also investigate how safe the compound is and how well the compound is tolerated, when it is taken alone and with another medication, omeprazole.
This study is not intended to improve the health of the volunteers, but is necessary for the further development of the compound.

Study objective

Primary:
to examine the effect of co-administration with omeprazole on the

pharmacokinetics of SSP-002358.

Secondary:
to provide additional safety information for SSP-002358 when administered alone or in combination with omeprazole.

Study design

Methodology
Design:
an open-label, randomized, two-period crossover drug interaction study

Procedures and assessments
Screening:
medical and medication history, physical examination, vital signs, height, weight, 12-lead ECG, clinical laboratory, HBsAg, anti HCV, anti-HIV 1/2, pregnancy test (females only) and urine drug and alcohol screen.

Observation period:
each period in clinic from -17 h up to 48 h after drug administration

Blood sampling:
Serial blood sampling through 48 h post-dose

Safety assessments:
adverse events; vital signs; physical examination, 12-lead ECG, clinical laboratory and pregnancy test

Bioanalysis:
analysis of plasma SSP-002358 samples using a validated method by Sponsor

Intervention

Study Medication
Active substance: SSP-002358
Activity : 5-HT4 receptor agonist
Indication : gastroesophageal reflux disease
Strength : 0.5 mg
Dosage form: tablets

Active substance: omeprazole
Activity: proton pump inhibitor
Indication: gastroesophageal reflux disease and ulcers
Strength: 40 mg
Dosage form: capsules

Treatments
Regimen A: a single oral dose of 1 mg SSP-002358
Regimen B: a single oral dose of 1 mg SSP-002358 and a single dose of 40 mg omeprazole

Study burden and risks

Not applicable.

Contacts

Public
Shire-Movetis NV

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18 - 55 year, BMI 18.5 - 30.0 kg/m2; no smoking.

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 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 in the 10 months prior the start of this study.

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):	31-08-2011
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Losec
Generic name:	Omeprazole
Product type:	Medicine
Brand name:	Not Applicable
Generic name:	Not Applicable

Ethics review

Approved WMO Date:	01-08-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-08-2011
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	EUCTR2011-001565-41-NL
CCMO	NL37509.056.11
Other	zal nog geregistreerd worden op www.clinicaltrials.gov