A SINGLE-CENTER, SINGLE-DOSE, OPEN-LABEL, THREE-WAY-CROSSOVER STUDY TO EVALUATE THE PHARMACOKINETICS OF THE HP-3070 PATCH (ASENAPINE TRANSDERMAL DRUG DELIVERY SYSTEM) FOLLOWING 24-HOUR APPLICATION COMPARED TO SINGLE-DOSE SYCREST® 5 MG (ASENAPINE, SUBLINGUAL) IN HEALTHY ADULT MALE AND FEMALE SUBJECTS

Published: 13-09-2012
Last updated: 26-04-2024

The main purpose of the study is to investigate whether the transdermal patch system HP-3070 shows blood concentrations of asenapine that make this route of administration suitable for clinical use. The transdermal route of administration is likely...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON36902

Source
ToetsingOnline

Brief title
HP -3070 Patch relative bioavailability study

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder, Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Noven Pharmaceuticals, Inc.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: asenapine maleate, HP -3070 patch

Outcome measures

Primary outcome

To evaluate the pharmacokinetics (PK) and relative bioavailability of asenapine following 24-hour (h) application of HP-3070 transdermal patches (containing 3.6 or 4.8 mg asenapine maleate) in healthy adult male and female subjects

Secondary outcome

To compare the PK profile of asenapine following application of two different HP-3070 transdermal patches (3.6 and 4.8 mg of asenapine maleate) to that of a single sublingual (SL) dose of Sycrest® (5 mg asenapine tablet) in healthy adult male and female subjects

To assess skin irritation, discomfort, patch adhesion, adhesive residue, and difficulty of patch application to skin and removal from liner of HP-3070 transdermal patch following 24 h application in healthy adult male and female

subjects

To evaluate apparent dose and percentage asenapine maleate released from HP-3070 transdermal patch following 24 h application in healthy adult male and female subjects

To assess the safety and tolerability of HP-3070 transdermal patch following 24 h application, and of a single SL dose of Sycrest® 5 mg in healthy adult male and female subjects

Study description

Background summary

HP-3070 is a new dosing form in the form of a transdermal patch which contains Asenapine that may eventually be used for the treatment of schizophrenia and bipolar disorder. HP-3070 as a patch with Asenapine is not registered as a drug and has not been given to humans before. Asenapine in an other dosing form (sublingual tablet) however is registered as a drug en is sold in the US onder the brand name Saphris®for the treatment of schizophrenia and bipolar disorder. In the EU this is sold under the brand name Sycrest® for bipolar disorder only. You will receive a patch with Asenapine twice, and once Sycrest as a sublingual tablet.

Study objective

The main purpose of the study is to investigate whether the transdermal patch system HP-3070 shows blood concentrations of asenapine that make this route of administration suitable for clinical use. The transdermal route of administration is likely to improve some issues involved in the oral administration of Asenapine such as numb feeling of the mouth / tongue. In addition, local and general tolerability of the HP-3070 transdermal patch and general tolerability of Sycrest® will be investigated.

Study design

HP-3070 3-way crossover PK study in which the dosing of asenapine as a patch application is compared with the dosing of asenapine as a sublingual tablet

Intervention

period 1: sublingual tablet with asenapine dosed once on dag 1
period 2: transdermal patch application with 3.6 mg asenapine for 24 hours on day 1
period 3: transdermal patch application with 4.8 mg asenapine for 24 hours on day 1

Study burden and risks

During this study several assessments will be performed that may be considered as a burden.

Asenapine has never been administered to humans through the HP-3070 system. Though local tolerability was good in animal experiments, local skin irritation may be a side-effect of HP-3070 patches.

Asenapine administered through a sublingual tablet has well-documented side effects of which the most important are: sleepiness, dizziness, postural dizziness / fainting, anxiety, oral numbness / numbness of the tongue / oral paraesthesia (tingling / burning sensation), spasm of the tongue, abnormal taste, akathisia (motor restlessness, inability to sit still), dystonia (involuntary muscle contractions that cause twisting and repetitive movements or abnormal postures), muscular stiffness, low blood pressure. To a lesser extent: hypersensitivity reactions including anaphylaxis, slow pulse rate / abnormal heart rhythm.

With the doses used in this study no serious adverse effects are expected. The occurrence of known or other (unknown) effects cannot be excluded. All potential drugs cause adverse events to some extent. Therefore subjects should take into account that some risks are still unknown at this moment

Contacts

Public
Noven Pharmaceuticals, Inc.

Empire State Building, 37th Floor 350 Fifth Avenue
New York NY10118
US
Scientific

Noven Pharmaceuticals, Inc.

Empire State Building, 37th Floor 350 Fifth Avenue
New York NY10118
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Gezonde mannen en vrouwen
18-45 jaar
niet rokend
BMI 18-30 incl

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 in the 10 months prior the start of this study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2012
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	asenapine maleate
Generic name:	n/a
Product type:	Medicine
Brand name:	asenapine maleate
Generic name:	sycrest
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-09-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	26-09-2012
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	EUCTR2012-003578-17-NL
CCMO	NL41995.056.12