AN OPEN LABEL STUDY TO EVALUATE THE PHARMACOKINETICS OF ASP7035 AFTER A SINGLE ORAL DOSE OF 14C-LABELED ASP7035 IN HEALTHY MALE SUBJECTS

Published: 22-07-2010
Last updated: 03-05-2024

Primary:- to evaluate the pharmacokinetics, in particular the routes and extent of metabolism and excretion, of the study medication after a single oral dose of 1 mg 14C-labeled study medicationSecondary: -to identify the metabolic profile of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON34187

Source
ToetsingOnline

Brief title
ASP7035 MB

Condition

- Renal disorders (excl nephropathies)

Synonym
Excessive night-time urination

Research involving
Human

Sponsors and support

Primary sponsor: Astellas Pharma

Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: ASP7035, Urine production

Outcome measures

Primary outcome

Radiokinetics

Pharmacokinetics

Safety

Tolerability

Secondary outcome

n.a.

Study description

Background summary

The drug to be given is a new, investigational compound that may eventually be used for the treatment of excessive night-time urination. The need to get up during the night in order to urinate is highly associated with for example aging, medication usage, diabetes mellitus and sleep disturbance. The compound is expected to reduce urinating by decreasing the water excretion in the kidneys.
No causal therapy for excessive night-time urination is available. A drug with a similar mode of action, however, is used at the moment. The drug is expected to have a better, more predictable efficacy and safety profile.

Study objective

Primary:
- to evaluate the pharmacokinetics, in particular the routes and extent of metabolism and excretion, of the study medication after a single oral dose of 1 mg 14C-labeled study medication

Secondary:

-to identify the metabolic profile of the study medication in human, blood, plasma, urine and feces after a single oral dose of 1 mg 14C-labeled study medication
-to evaluate safety and tolerability after a single oral dose of 1 mg 14C-labeled study medication

Study design

Design:
An open-label ADME study in six healthy male subjects receiving a 14C labeled, single oral dose of the study medication, containing approximately 2.8 MBq radioacarbon

Procedures and assessments
Screening and follow-up:
Clinical laboratory, vital signs (in triplicate at screening), physical examination, 12-lead ECG; at eligibility screening: medical history, alcohol and drug screen, HBsAg, anti HCV, anti-HIV 1/2; physical examination, alcohol and drug screen, clinical laboratory, vital signs and 12-lead ECG to be repeated upon admission

Observation period:
One period in clinic from -17 h up to 120 h after drug administration and a possible extension to Day 9 if discharge criteria (recovery of administered radioactivity *95% and radioactivity in urine and faeces is below acceptable limits <50 dpm/mL in urine or <75 dpm in 100 mg original faeces) have not been met on Day 6; if after the 3-day prolongation, the discharge criteria have still not been met, subjects will be requested to continue collecting all their urine and/or faeces at home

Blood sampling:
For pharmacokinetics of the study medication: pre-dose and up to 48 h post-dose
For total radioactivity in plasma and blood: pre-dose and up to120 h post-dose and each 24 h in case of prolonged in-house stay
For metabolic profiling: pre-dose and up to 120 h post-dose and each 24 h in case of prolonged in-house stay
For biobanking: pre-dose

Urine sampling:
For pharmacokinetics of of the study medication, total radioactivity and metabolic profiling: pre-dose and intervals 0-2, 2-4, 4-8, 8-12, 12-24 h post-dose and 24 h collection intervals up to discharge

Faeces sampling:
For pharmacokinetics of the study medication, total radioactivity and metabolic profiling: pre-dose and 24 h collection intervals up to discharge

Expired air sampling:
Pre-dose and up to 120 h post-dose and each 24 h in case of prolonged in-house stay

Safety assessments:
Adverse events: throughout the study; clinical laboratory, 8, 24 and 120 h post-dose; vital signs and 12-lead ECG: pre-dose and 2, 8, 24 and 120 h post-dose

Bioanalysis:
Analysis of the study medication in plasma, urine and faeces samples using validated methods by PRA
analysis of total radioactivity in plasma, blood, urine, faeces and expired air using validated methods by PRA
metabolic profiling by PRA

Intervention

Active substance: ASP7035 and [14C]-ASP7035

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

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

- Healthy male
- 18 - 55 years of age, inclusive
- BMI 18.5 - 30.0 kg/m2
- Non-smoker, or not more than 10 cigarettes for at least three months before drug administration

Exclusion criteria

Suffering from: hepatitis B, 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 90 days from the start of the study. In case of donating more than 1.5 liters of blood in the 12 months prior the start of this study. Participation is also not permitted when participated in more than 3 other drug studies in the 10 months prior to 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):	02-08-2010
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
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Application type:	First submission
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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	EUCTR2010-019385-84-NL
CCMO	NL33138.056.10