An open-label, mass balance study to investigate the absorption, metabolism and excretion of [14C]-EYP001a after a single oral dose to healthy male subjects

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Primary objectives:To determine the ratio of parent drug to metabolites in the circulation following administration of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity.Profiling of EYP001a metabolites in blood, urine and...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48170

Source
ToetsingOnline

Brief title
CS0315 Enyo

Condition

- Other condition

Synonym
chronic hepatitis B virus (HBV) infection and non-alcoholic steatohepatitis (NASH).

Health condition

Chronic liver diseases, HBV/NASH

Research involving

Human

Sponsors and support

Primary sponsor: ENYO Pharma SA
Source(s) of monetary or material Support: Enyo Pharma

Intervention

Keyword: [14C]-EYP001a, Absorption, excretion, metabolism

Outcome measures

Primary outcome

The following parameters will be calculated, whenever possible and appropriate and taking into account the last time point where detectable radioactivity counts were observed:

Radioactivity-time profiles in whole blood and plasma.

Maximum observed total radioactivity in plasma and whole blood (Cmax).

Time from dosing to peak total radioactivity in plasma and whole blood (tmax).

Area under the total radioactivity-time curve in plasma and whole blood from time zero to 24 hours (AUC0-24).

Area under the total radioactivity-time curve in plasma and whole blood from time zero to the time of the last quantifiable drug concentration (AUC0-tz).

Area under the total radioactivity-time curve in plasma and whole blood from time zero to infinity (AUC0-inf).

[14C]-metabolic profile and identification of metabolites in plasma.

[14C]-radioactivity in urine.

[14C]-metabolic profile and identification of metabolites in urine.

[14C]-radioactivity in feces.

[14C]-metabolic profile and identification of metabolites in feces.

Secondary outcome

Vital signs values;

Clinical laboratory values;

Number of subjects with adverse events (AEs);

12-lead ECG values.

Study description

Background summary

ENYO Pharma is developing EYP001a, a selective synthetic, non-bile salt, carboxylic acid farnesoid X receptor (FXR) agonist, for the treatment of chronic hepatitis B virus (HBV) infection and non-alcoholic steatohepatitis (NASH). Chronic liver diseases are major public health problems [1]. Current, but probably undervalued, worldwide estimations show that 844 million people have chronic liver diseases, with a mortality rate of 2 million deaths per year. While viral chronic liver diseases such as HBV infection are predominant in Asia, Africa and Latin America, emergent metabolic diseases (i.e., non-alcoholic fatty liver disease (NAFLD), and NASH) are the most common causes of chronic liver diseases in Western countries. Patients with NASH and chronic HBV infection have increased rates of liver-related mortality due to the development of complications, including fibrosis, cirrhosis, and hepatocellular carcinoma (HCC). There is therefore an urgent need for improved treatment options for both chronic liver diseases.

Study objective

Primary objectives:
To determine the ratio of parent drug to metabolites in the circulation following administration of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity.
Profiling of EYP001a metabolites in blood, urine and feces.
To determine the mass balance of drug-related materials following administration of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity.
To determine the primary route of excretion of drug-related materials following administration of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity.

To determine the total radioactivity versus time profile in plasma and whole blood following administration of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity.

Secondary objective:
To investigate the safety and tolerability of a single oral dose of 400 mg [14C]-EYP001a containing 100 µCi radioactivity in healthy subjects.

Study design

The present study is designed to investigate the absorption, metabolism, excretion as well as safety/tolerability of EYP0001a following the administration of a single oral dose to healthy male volunteers.

Intervention

[14C]-ENP001a, single dose

Study burden and risks

Since this study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IMPD for further information.

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. Able to provide informed consent to participate in this study after reading the participant information sheet and informed consent form and after having the opportunity to discuss the study with the Investigator or designee.
2. Healthy and free from clinically significant illness or disease as determined by medical history, physical examination, laboratory and other tests at Screening.
3. Male Caucasian subjects, aged 18 to 60 years (inclusive) at Screening.

Exclusion criteria

1. Any finding of the medical examination (including blood pressure, pulse rate and ECG) deviating from normal and of clinical relevance.
2. History or current clinically significant gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunologic, hormonal disorders.
3. History of any major surgery within the last 4 weeks before participation in this study or any bone fracture within the last 2 months.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-07-2019
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-07-2019
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	EUCTR2019-001304-37-NL
CCMO	NL70237.056.19

Study results

Date completed: 05-08-2019

Results posted: 08-09-2020

First publication
04-08-2020