A single-dose, open label, randomized, three-way cross-over study in healthy volunteers to characterize the pharmacokinetics of the 300 mg trientine capsule and to assess the effect of dissolution rate and the effect of food on the pharmacokinetics of trientine.

Published: 11-06-2018
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Primary objectives:To characterize the pharmacokinetics of the 300 mg trientine capsule with a fast dissolution profile.To assess the effect of dissolution rate on the pharmacokinetics of trientine.To assess the effect of food on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON46237

Source
ToetsingOnline

Brief title
180194-CS0298 Univar

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym
hepatolenticular degeneration, Wilson's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: capsule, Pharmacokinetics, trientine

Outcome measures

Primary outcome

PK: Cmax, AUC0-t, AUC0-*, Tmax, t1/2 and Kel for trientine.

Secondary outcome

PK: Cmax, AUC0-t, AUC0-*, Tmax, t1/2 and Kel for MAT and DAT

PD (for treatments A and C only): urinary copper excretion, serum copper and

ceruloplasmin

Safety: AEs (clinical relevant changes in VS, ECGs and laboratory parameters

should be reported as AEs)

Study description

Background summary

Wilson's disease (WD) is a rare autosomal recessive condition caused by mutations of the ATP7B gene, a gene that encodes for the Wilsons protein, a metal-transporting P-type adenosine triphosphate (P-type ATP) (Ala et al 2007). First symptoms of WD symptoms usually appear between the ages of 6 and 20 years and males and females are equally affected. WD occurs in approximately 1 to 4 per 100,000 people (Ala et al 2007). The therapy is aimed to reduce the serum copper levels by reducing the intake with a low copper diet, reducing the copper absorption by treatment with zinc acetate, and by the use of chelating agents such as D-penicillamine and trientine dihydrochloride that bind the free copper and facilitate its excretion from the body. Early diagnosis and

life-long treatment is important to prevent serious long-term disability and life threatening complications.

Study objective

Primary objectives:
To characterize the pharmacokinetics of the 300 mg trientine capsule with a fast dissolution profile.
To assess the effect of dissolution rate on the pharmacokinetics of trientine.
To assess the effect of food on the pharmacokinetics of trientine.

Secondary objectives:
To assess the pharmacokinetics of the metabolites of trientine after administration of trientine capsules with different dissolution rates and in fed and in fasted conditions.
To assess and compare the pharmacodynamics after administration of trientine capsules with different dissolution rates.
To assess and compare the safety and tolerability after administration of trientine capsules with different dissolution rate and in fed and fasted conditions.

Study design

A single dose, open label, randomized, two-way cross-over study in healthy volunteers.

Intervention

Trientine dihydrochloride 300 mg capsule.

Study burden and risks

The dosage levels of the study drug are based on a previous clinical trial conducted by the sponsor. The risk to health at the chosen dose is limited, but the patients may experience any of the side effects in the ICF or symptoms that have not been reported before.
Volunteers health is closely monitored during the study to minimize these risks. If the volunteers experience side effects, the investigator will treat them where necessary. If new information is available on the safety of the study medication, the volunteers are informed as soon as possible. The blood collection procedure is not dangerous.

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 or female subjects;Females must not be pregnant or breastfeeding and must be postmenopausal or agree to use an acceptable form of birth control;Aged 18 to 75 years inclusive at screening.;For more inclusion criteria a reference is made to the protocol.

Exclusion criteria

Has smoked more than 5 cigarettes or equivalents tobacco products per day within 14 days prior to the first dose of study medication.;History or presence of drug or alcohol abuse within the past 5 years. ;For more exclusion criteria a reference is made to the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2018
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Trientine dihydrochloride
Generic name:	Trientine

Ethics review

Approved WMO Date:	11-06-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-06-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	06-07-2018
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	EUCTR2018-001982-17-NL
CCMO	NL66134.056.18

Study results