A PHASE 1, OPEN-LABEL STUDY TO ASSESS THE MASS BALANCE AND PHARMACOKINETICS OF [14C]-IMU-838 IN HEALTHY MALE SUBJECTS

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Ethical review	Approved WMO
Status	Completed
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON51590

Source
ToetsingOnline

Brief title
Mass balance study of [14C]-IMU-838

Condition

- Central nervous system infections and inflammations

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Immunic AG

Source(s) of monetary or material Support: Pharmaceutical Industry.

Intervention

Keyword: [14C]-IMU-838, Healthy Volunteers

Outcome measures

Primary outcome

To assess the mass balance (recovery), and routes and extent of elimination of

a single oral dose of 45 mg [14C]-IMU-838 containing approximately 0.1998 MBq

(5.4 µCi) of total radioactivity (TRA) in healthy male subjects

Secondary outcome

To assess the safety and tolerability of a single oral dose of 45 mg [14C] IMU

838 containing approximately 0.1998 MBq (5.4 µCi) of TRA in healthy male

subjects

To further characterize the pharmacokinetics (PK) of a single oral dose of 45

mg [14C]-IMU-838 in healthy male subjects

To identify and characterize metabolites of [14C]-IMU-838 in plasma, urine, and

feces

Study description

Background summary

Vidofludimus calcium (IMU-838) is a compound that may potentially be used for the treatment of multiple sclerosis (including progressive multiple sclerosis, relapsing multiple sclerosis, and relapsing remitting multiple sclerosis), as well as a rare chronic liver disease (also known as primary sclerosing

cholangitis), inflammatory bowel disease (ie, ulcerative colitis and Crohn*s disease), and hospitalized patients with moderate coronavirus disease 19 (COVID-19).

IMU-838 has been used by humans before. In addition, IMU-838 has been extensively investigated and tested in the laboratory in various animal models (including mouse, rat, and dog).

The active substance of IMU-838 is vidofludimus calcium. It is a compound that inhibits the human enzyme dihydroorotate dehydrogenase (DHODH). Inhibiting DHODH causes specific changes at the cellular level, reduces inflammation associated with multiple sclerosis and may be beneficial for a variety of diseases. These diseases include viral infections, chronic inflammatory and autoimmune diseases.

Study objective

In this study we will investigate the safety of the study compound IMU-838 and how well it is tolerated when it is used by healthy subjects. Please note that when the term *study compound* is used in this document, we mean IMU-838.

The study will also investigate how quickly and to what extent IMU-838 is absorbed, transported, and eliminated from the body (this is called pharmacokinetics). For this study, IMU-838 is radioactively labeled with carbon-14 (14C) to trace the study drug in blood, urine, and feces and to estimate routes and extent of excretion of radioactivity.

Study design

The study takes a maximum of 9 weeks from the screening to the follow-up. A total of 7 adult men will participate in the study.

Day 1 is the day of receiving study drug (IMU 838). For the research it is necessary to stay in the research center for 1 period of 11 days (10 nights). If necessary, this period can be extended by a maximum of 4 days (3 nights).

The time between the examination and the final stay depends on the amount of radioactivity remaining in the urine and faeces at the end of the examination (Day 10). The amount of radioactivity in urine and faeces is measured daily from Day 1. If on Day 10 the radioactivity levels in urine and faeces are below predefined levels, one may leave the study center. If eligibility criteria are not met on Day 10, patients must remain in the study center for up to 4 additional days (Days 11 to 14) until eligibility criteria are met. If discharge criteria are still not met on Day 14, the person will be discharged and asked to collect stool samples at home 24 hours prior to the stay and bring these samples to the Clinical Research Center during the 24-hour visit on Days

21-22 , 28-29 and/or 35/36. Urine and stool samples are collected during the 24-hour visits. For these collection moments, people are expected in the research center on these days. The volunteer receives a follow-up phone call 3 to 7 days after the last stay

The volunteer will receive 45 mg of [14C]-IMU-838 as a 250 milliliter (ml) drink by mouth. After administration of the study drug, the vial will be rinsed twice with 50 ml of water, which should also be drunk.

Intervention

On Day 1; 45 mg of [14C] IMU-838 as an oral solution, once

Study burden and risks

Blood collection
Blood tests can hurt or cause bruising. The use of an indwelling cannula can sometimes lead to inflammation, swelling, hardening of the artery, or blood clotting and bleeding around the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

All in all, we take approximately 402 milliliters (ml) of blood from the test to the follow-up. This amount does not cause problems in adults.

ECG
Electrodes are placed on the arms, chest and legs to make a heart film. Prolonged application of these electrodes may cause skin irritation.

Fasting
If you have to fast for a long time during the study, this can lead to complaints such as dizziness, headache, stomach complaints or fainting.

Coronavirus tests
Samples for the coronavirus test will be taken from the back of the nose and throat with cotton swabs. Taking the samples only takes a few seconds, but can cause discomfort and an unpleasant feeling. Taking a sample from the back of the throat can cause gagging. When the sample is taken from the back of the nose, a stinging sensation may be experienced and the eyes may water.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Sex: Male subjects.
2. Age: 18 to 45 years, inclusive, at screening.
3. Body mass index (BMI): 18.0 to 30.0 kg/m2, inclusive, at screening.
4. Weight: >=50 kg at screening.

Exclusion criteria

1. Previous participation in the current study.
2. Employee of ICON plc or the Sponsor.
3. History of relevant drug and/or food allergies.
4. Using tobacco products within 60 days prior to the drug administration.
5. History of alcohol abuse or drug addiction (including soft drugs like cannabis products) in the past 2 years.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-01-2023
Enrollment:	7
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	16-01-2023
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	EUCTR2022-003181-21-NL
CCMO	NL83270.056.22

Study results

Date completed: 27-03-2023

Results posted: 19-02-2024

First publication
22-01-2024