A Phase 1, Single-blind, Randomized, Parallel-group Study in Healthy Participants to Investigate the Single-dose Pharmacokinetics, Safety and Tolerability of Rilpivirine After Subcutaneous Administration of a Rilpivirine Extended-Release Suspension alone, and of Rilpivirine and Cabotegravir After Co-administration with Cabotegravir Extended-Release Suspension

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To characterize the single-dose pharmacokinetic (PK) of RPV after SC administration of RPV LA suspensions with different doses and/or different particle size (PS) to support further dose and formulation selection, in healthy adult participants.To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON51507

Source
ToetsingOnline

Brief title
A Study of Rilpivirine Extended-Release Suspension in Healthy Participants

Condition

- Immunodeficiency syndromes

Synonym
Human immunodeficiency virus syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag International NV
Source(s) of monetary or material Support: Pharmaceutical Industry.

Intervention

Keyword: Cabotegravir, Human Immunodeficiency Virus 1, rilpivirine

Outcome measures

Primary outcome

Characterize the single-dose pharmacokinetic (PK) of rilpivirine (RPV) after SC

administration of rilpivirine long-acting.

Characterize the single-dose pharmacokinetic (PK) of cabotegravir (CAB) after

SC administration of cabotegravir long-acting

Secondary outcome

Evaluate the safety and tolerability of SC administration of rilpivirine

long-acting.

Adverse events, injection site reactions, vital signs, physical examination,

laboratory parameters, nd electrocardiogram (ECG) parameters.

Study description

Background summary

The drug being studied is called rilpivirine long-acting (RPV LA).

Rilpivirine is currently approved as an intramuscular injection (IM, into the muscle) in combination with cabotegravir injection, for the treatment of HIV-1 infection.

The current study will explore giving RPV LA subcutaneously (SC, under the skin) at different doses and/or formulations.

Study objective

To characterize the single-dose pharmacokinetic (PK) of RPV after SC administration of RPV LA suspensions with different doses and/or different particle size (PS) to support further dose and formulation selection, in healthy adult participants.
To characterize the single-dose PK of RPV after subcutaneous co-administration of CAB LA with RPV LA, in healthy adult participants.
To characterize the single-dose PK of CAB after subcutaneous co-administration of CAB LA with RPV LA, in healthy adult participants.

Study design

For the study it is necessary that subjects stay in the research center for 7 days (6 nights). This will be followed by 20 visits to the research center, including a follow-up visit.

Intervention

Panel A: Rilpivirine (RPV) Long-acting (LA)
Participants will receive one dose of RPV LA (formulation 1) under different conditions (Treatment A and B) on Day 1.

Panel B: RPV LA
Participants will receive one dose of RPV LA (formulation 2) under different conditions (Treatment C and D) on Day 1.

Panel C: RPV LA
Participants will receive one dose of RPV LA (formulation 1) under different conditions (Treatment E and F) on Day 1, based on interim data of Panel A and/or B.

Panel D: RPV LA

Participatns will receive one dose of RPV LA (formulation 2) under different conditions (Treatment G and H) on Day 1, based on interim data of Panel A and/or B.

Panel E:
Participants will receive one dose of RPV LA (formulation 1) and a single dose of CAB LA (Treatment I)

Study burden and risks

Blood draw
Taking blood samples may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.

In total, we will take less than 220 milliliters (mL) of blood from screening to follow-up (if no unscheduled blood draws). This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time at once. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Heart tracing
There is generally no risk with having an ECG. The sticky patches may pull the skin or cause redness or itching.

Coronavirus test
With a sterile swab, a smear will be made of the mucous membranes at the back of the nose. This is done by inserting the swab into the nostril until resistance is felt; the swab is then rotated for sample collection and removed from the nostril. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause subject to gag. When the sample is taken from the back of the nose, they may experience a stinging sensation and the eyes may become watery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Each potential participant must satisfy all of the following criteria to be enrolled in the study:
1. Participant must be 18 to 55 years of age, extremes included, at screening.
2. Participant must be healthy on the basis of physical examination, medical history, vital signs, and 12-lead ECG performed at screening.
3. Participant must be healthy on the basis of clinical laboratory tests performed at screening.
4. Body mass index between 18.0 and 35.0 kg/m2, extremes included, and body weight not less than 50.0 kg at screening.
5. Male or female.

Further criteria apply

Exclusion criteria

1. Participant with a history of or current illness that, in the opinion of the investigator, might confound the results of the study or pose an additional risk in administering study intervention to the participant or that could prevent, limit or confound the protocol specified assessments.
2. Participant has a history of malignancy within 5 years before screening (exceptions are squamous and basal cell carcinomas of the skin and carcinoma in

situ of the cervix, or malignancy, which is considered cured with minimal risk of recurrence).
3. Participant has known allergies, hypersensitivity, or intolerance to Rilpivirine, rHuPH20, or their excipients
4. Participant has a history of clinically relevant arrhythmias or history of risk factors for Torsade de Pointes .
5. Participants with the following ECG findings, if clinically significant: abnormal PR, QRS, and QTc intervals; rhythm abnormalities; evidence of acute ischemic changes.

Further criteria apply

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2021
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	n.a.
Generic name:	Cabotegravir
Product type:	Medicine
Brand name:	n.a.

Generic name:	Rilpivirine co-administered with recombinant human hyaluronidase (rHuPH20)
Product type:	Medicine
Brand name:	REKAMBYS
Generic name:	Rilpivirine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-11-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-11-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-03-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-06-2022
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	26-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-03-2024
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	EUCTR2021-002697-31-NL
CCMO	NL79472.056.21