This document provides a short summary of this study for a general audience. You can find more information in the scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study names

Short Title: A study to compare cabotegravir and rilpivirine when given once every 8 weeks with once every 4 weeks to adults living with HIV infection.

Full Scientific Title: A phase IIIb, randomised, multicentre, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety, and tolerability of long-acting cabotegravir plus long-acting rilpivirine administered every 8 weeks or every 4 weeks in HIV-1-infected adults who are virologically suppressed.

ViiV Healthcare Study Number: 207966

Who sponsored this study?

ViiV Healthcare
GSK Clinical Support Help Desk
Website: clinicalsupporthd.gsk.com/contact.html
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When was this study done?

The study started in October 2017. Enrolment is closed, but the study was ongoing when this summary was finalised.

What was the main objective of this study?

Human immunodeficiency virus type 1 (HIV) damages the body's defence system (immune system). It weakens the ability to fight infections and increases the risk of developing diseases. Doctors monitor the amount of HIV in the body (viral load) by measuring HIV RNA levels in the blood.

Antiretroviral medicines treat HIV infection by controlling the viral load. Researchers consider that these medicines worked well if the patients' viral loads reduced and remained undetectable (less than 50 copies per millilitre [c/mL]).

In this study, researchers compared cabotegravir (CAB) and rilpivirine (RPV) injections when given once every 8 weeks with once every 4 weeks to adults living with HIV infection. Researchers wanted to assess how well these medicines worked and how safe they were.

Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Men and women with HIV infection were included in the study if they:

- Were at least 18 years old.
- Received antiretroviral medicines continuously for at least six months before starting the study.
- Had viral load levels that were both controlled for a year and reduced to undetectable levels before starting the study.

Men and women were excluded from the study if they had:

- Known resistance to certain medicines used to treat HIV infection.
- Any other disease(s) or taken any medicine(s) that the study doctor thought would affect the results of the study.

Some of the patients in this study had taken part in a previous study (Study 201585).

Overall, 1045 patients received at least one dose of the study medicines. The study included 765 patients (73%) who were assigned male at birth and 280 patients (27%) who were assigned female at birth. Of these, 757 patients identified as male and 288 patients identified as female. The average age was 42 years. The youngest patient was 19 years old and the oldest patient was 83 years old.

For more detailed information about the patients included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

Which medicines were studied?

On Day 1, patients were placed in one of the following two treatment groups by chance (randomisation).

- CAB and RPV once every 8 weeks group: Patients received CAB and RPV injections once every 8 weeks up to Week 100.
- CAB and RPV once every 4 weeks group: Patients received CAB and RPV injections once every 4 weeks up to Week 100.

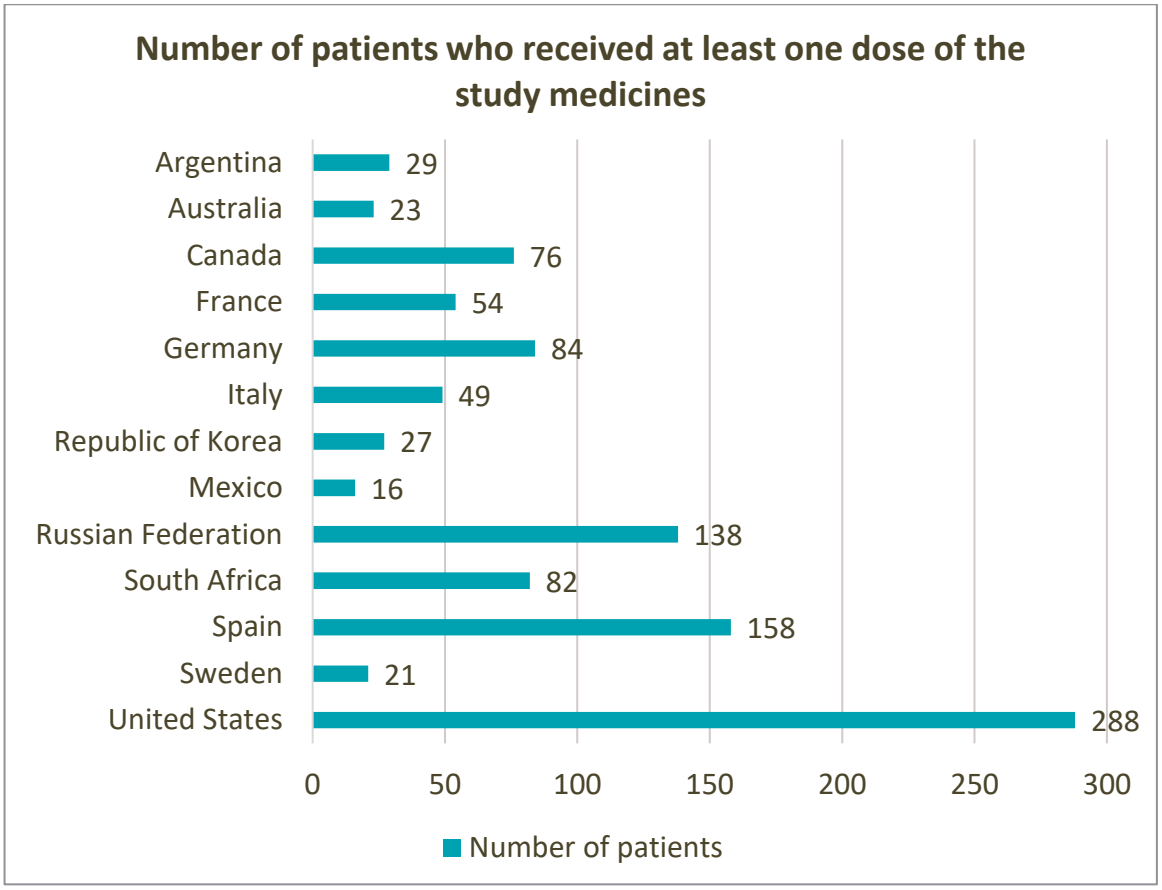
Patients who had never received CAB and RPV were given these study medicines as tablets for the first four weeks. After that, they received CAB and RPV injections.

The patient and the study doctor knew which treatment the patient received.

After Week 100, patients could choose to continue receiving CAB and RPV injections in the study until these study medicines were available in their country.

Where was this study done?

Study sites were in 13 countries.



What were the main results of the study?

Study doctors collected blood samples and measured patients' viral loads.

The table below shows the results for patients who had viral load assessed as:

- Detectable: 50 c/mL or more at Week 48 or at their last test before they stopped taking part in the study.
- Undetectable: Less than 50 c/mL at Week 48.

Number of patients (percent) by viral load		
	CAB and RPV	
	Once every 8 weeks group 522 patients	**Once every 4 weeks group 523 patients**
50 c/mL or more	9 (2%)	5 (1%)
Less than 50 c/mL	492 (94%)	489 (93%)

More information about the study results is available in the scientific results summaries (links to those summaries are provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summaries (links to those summaries are provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicines and/or injections. The side effects in this summary may be different to those in the Informed Consent for this study or other documents related to the study medicines.

The side effects in this summary have been reported from Day 1 to Week 100.

Serious side effects

Serious side effects were reported by four patients (less than 1%) in the CAB and RPV once every 8 weeks group and three patients (less than 1%) in the CAB and RPV once every 4 weeks group. None of these serious side effects were reported by more than one patient in either treatment group.

Non-serious side effects

Non-serious side effects were reported by 400 patients (77%) in the CAB and RPV once every 8 weeks group and 399 patients (76%) in the CAB and RPV once every 4 weeks group. The table below shows the non-serious side effects that were reported by 4% or more of patients.

Number of patients (percent) with non-serious side effects reported by 4% or more of patients		
	CAB and RPV	
	Once every 8 weeks group 522 patients	**Once every 4 weeks group 523 patients**
Injection-related non-serious side effects		
Pain	364 (70%)	358 (68%)
Lump	54 (10%)	87 (17%)
Hardness	40 (8%)	37 (7%)
Discomfort	34 (7%)	40 (8%)
Swelling	32 (6%)	26 (5%)
Itchiness	26 (5%)	24 (5%)
Study medicine-related non-serious side effects		
Fever	19 (4%)	25 (5%)
Feeling tired	7 (1%)	19 (4%)

How has this study helped patients and researchers?

Researchers concluded that CAB and RPV injections showed a similar response when given once every 8 weeks compared with once every 4 weeks to adults living with HIV infection. The side effects reported in this study were not unexpected and were limited in number.

This was a Phase III study. Phase III studies collect information about how well new medicines work and how safe they are. The results help government regulators make decisions about new medicines for their country.

Are there plans for further studies?

Other studies of CAB and RPV in adults living with HIV infection have been conducted and some are ongoing or planned.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study numbers associated with this study are shown below with internet links to scientific summaries.

The scientific summaries include more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events. When the study is complete, final results will be available in the scientific summaries.

Organisation and Website	Study Number
European Medicines Agency (www.clinicaltrialsregister.eu)	2017-002946-62[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03299049[2]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-002946-62
[2] https://clinicaltrials.gov/ct2/show/NCT03299049?term=NCT03299049&rank=1

make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating adults living with HIV infection.

The content for this document was finalised by ViiV Healthcare on 21 June 2021. The information in this summary does not include additional information available after this date.