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 a long-acting combination of cabotegravir and rilpivirine with current antiretroviral regimen in people living with HIV-1 infection.

Full Scientific Title: A phase III, randomised, multicentre, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen in HIV-1-infected adults who are virologically suppressed.

ViiV Healthcare Study Number: 201585

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 2016. 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-1) 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-1 in the body (viral load) by measuring the HIV-1 RNA levels in blood.

Antiretroviral medicines treat HIV-1 infection by controlling the viral load. Researchers consider that antiretroviral medicines worked well if the patients' viral load remained less than 50 copies per millilitre (c/mL).

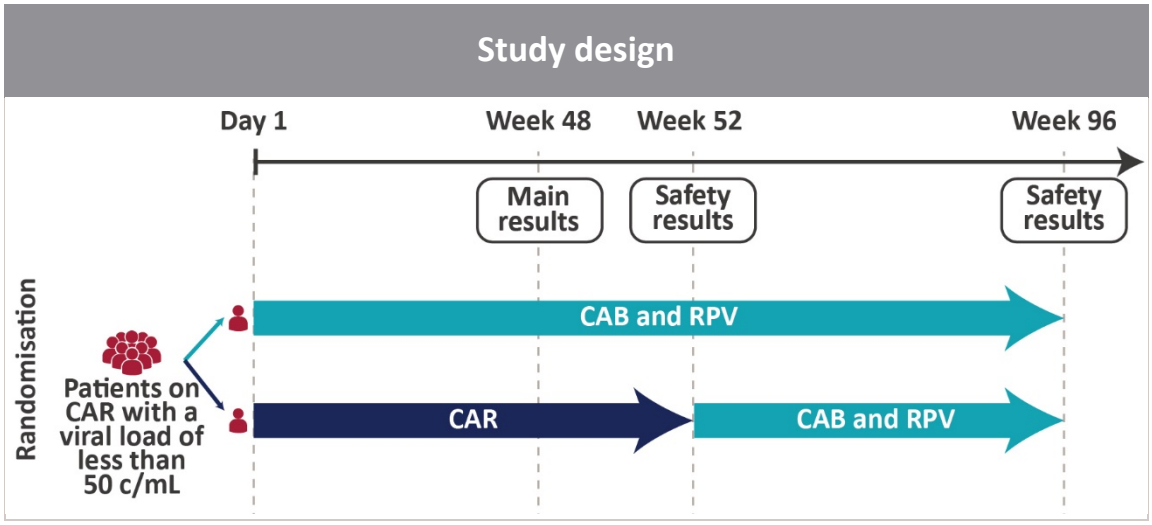
When this study started, people living with HIV-1 infection were being treated with three approved antiretroviral medicines. This was their current antiretroviral regimen (CAR). Researchers wanted to see how a combination of monthly cabotegravir (CAB) and rilpivirine (RPV) injections works in people living with HIV-1 infection compared with daily CAR tablets. They also assessed the safety of these medicines.

Which medicines were studied?

As shown in the figure below, on Day 1, patients were placed in one of the following two treatment groups by chance (randomisation):

- CAB and RPV group: Patients received daily CAB and RPV tablets for four weeks. Then they received monthly CAB and RPV injections.
- CAR group: Patients continued taking their daily CAR tablets for 52 weeks. Then they switched to monthly CAB and RPV injections.

The patients and study doctors knew which treatment they received. This is called an open-label study.



After Week 52, patients could choose to move to another similar study. Patients who remained in this study after Week 96 continued receiving CAB and RPV until approved in their country.

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-1 infection were included in the study if they:

- Were at least 18 years old.
- Had a viral load of less than 50 c/mL at least
  - once within six months before starting the study.
    AND
  - once between six to 12 months before starting the study.
- Received their CAR continuously (with no gap of one month or more) for at least six months before starting the study.
- Had a viral load of less than 50 c/mL on Day 1.

Men and women with confirmed viral load of less than 50 c/mL on Day 1 were excluded from the study if they had:

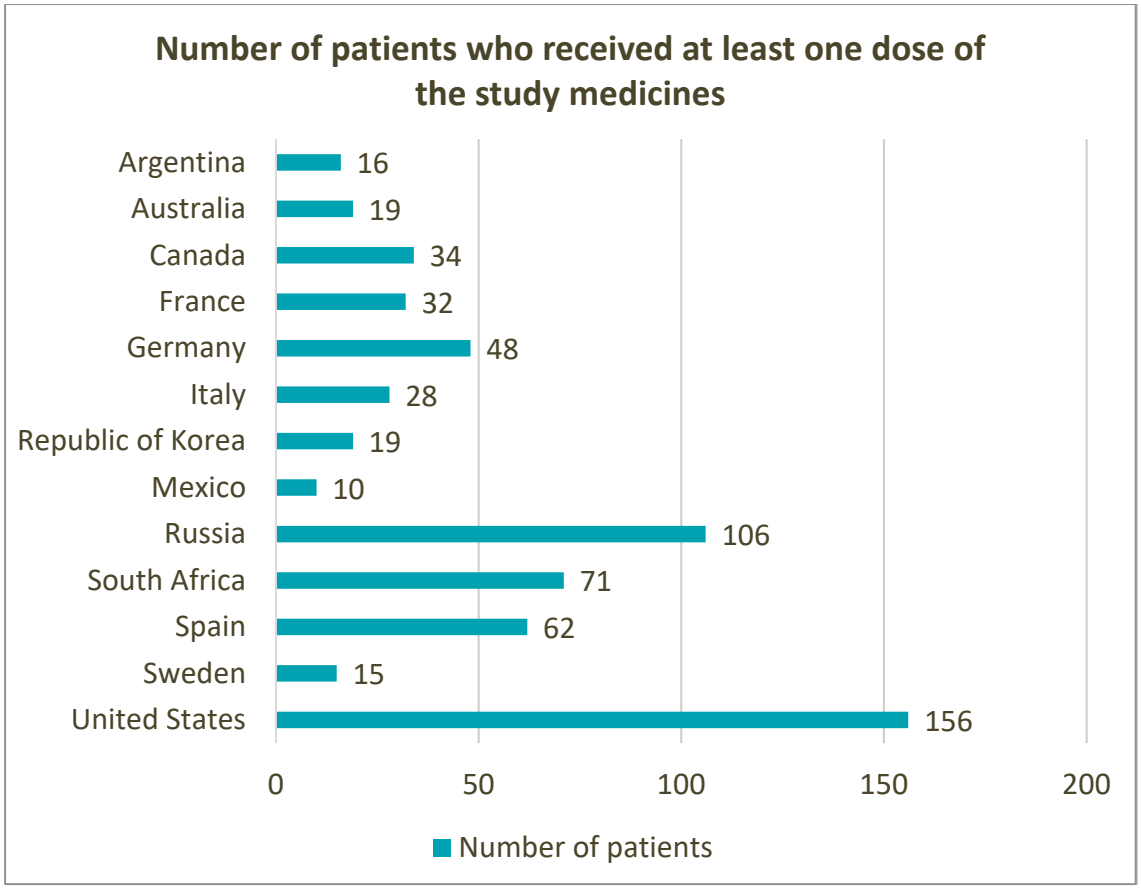
- A viral load of 50 c/mL or more within six months before starting the study.
- A viral load of 50 c/mL or more at least twice between six to 12 months before starting the study.
- A viral load of more than 200 c/mL at least once between six to 12 months before starting the study.
- Any other disease(s) or had taken any medicine(s) before starting the study, that the study doctor thought would affect the results of the study.

Overall, 616 patients received at least one dose of the study medicines. The study included 413 (67%) men and 203 (33%) women. The average age was 42 years. The youngest patient was 18 years old and the oldest patient was 82 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).

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 load on Day 1 and during the study.

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

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

Number of patients (percent) by viral load		
	CAB and RPV group 308 patients	**CAR group 308 patients**
50 c/mL or more	5 (2%)	3 (1%)
Less than 50 c/mL	285 (93%)	294 (95%)

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.

Side effects up to Week 52

No serious side effects were reported in the 308 patients in the CAB and RPV group. One patient (less than 1%) in the CAR group reported a serious side effect of having suicidal thoughts.

The table below shows the non-serious side effects that were reported by 4% or more of patients in the CAB and RPV group. No non-serious side effects were reported by 4% or more of patients in the CAR group up to Week 52.

Number of patients (percent) with non-serious side effects reported by 4% or more of patients up to Week 52	
	CAB and RPV group 308 patients
Injection-related non-serious side effects	
Pain	227 (74%)
Lump	36 (12%)
Hardness	29 (9%)
Swelling	22 (7%)
Redness	12 (4%)
Study medicine-related non-serious side effects	
Feeling tired	11 (4%)
Fever	11 (4%)
Headache	11 (4%)
Nausea	11 (4%)

Side effects after Week 52

Between Week 52 and Week 96, most patients in either treatment group chose to move to another similar study. Of the 616 patients, only 51 patients remained in this study at Week 96.

At Week 96, only 23 of 308 patients remained in the CAB and RPV group. Of the 308 patients in the CAR group, 174 patients switched from CAR to CAB and RPV at Week 52. Only 28 of these patients continued to receive CAB and RPV up to Week 96. No serious side effects were reported by patients in either treatment group after Week 52.

The non-serious side effects reported by patients in either treatment group after Week 52 were similar to those reported by patients in the CAB and RPV group up to Week 52. The most common side effects reported in both treatment groups after Week 52 were injection-related side effects.

How has this study helped patients and researchers?

The study showed that people living with HIV-1 infection receiving a combination of monthly CAB and RPV injections had a similar response in maintaining the viral load compared with patients taking their daily CAR tablets. The side effects reported in this study were not unexpected and were limited in number.

Are there plans for further studies?

Other studies of CAB and RPV in people living with HIV-1 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)	2016-001647-39[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT02951052[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 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 people living with HIV-1 infection.

The content for this document was finalised by ViiV Healthcare on 1 February 2021. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-001647-39/results

[2] https://clinicaltrials.gov/ct2/show/NCT02951052?term=NCT02951052&draw=2&rank=1