This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to compare a combination of dolutegravir and rilpivirine with antiretroviral regimens containing tenofovir on bone mineral density in patients with HIV-1 infection.

Full Scientific Title: An evaluation of bone mineral density in HIV-1-infected adult subjects switching from a tenofovir-containing antiretroviral therapy regimen to a dolutegravir plus rilpivirine regimen.

ViiV Healthcare Study Number: 202094

Who sponsored this study?

ViiV Healthcare
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 June 2015 and ended in August 2018.

What was the main objective of this study?

Human immunodeficiency virus type 1 (HIV-1) damages the body's defence system (immune system) and weakens the ability to fight infections and diseases.

Antiretroviral medicines are used to treat HIV-1 infection. Some people treated with antiretroviral medicines will lose strength in their bones. Researchers have seen this effect with a medicine called tenofovir.

In this study, researchers wanted to compare bone strength in patients taking dolutegravir (DTG) and rilpivirine (RPV) with patients taking their current antiretroviral regimens (CAR), which was a combination of three or more antiretroviral medicines including tenofovir.

How was this study designed?

Some patients who were accepted to take part in one of the parent studies (201636 or 201637) could also be in this study. Links to the scientific summaries of these studies are provided at the end of this document.

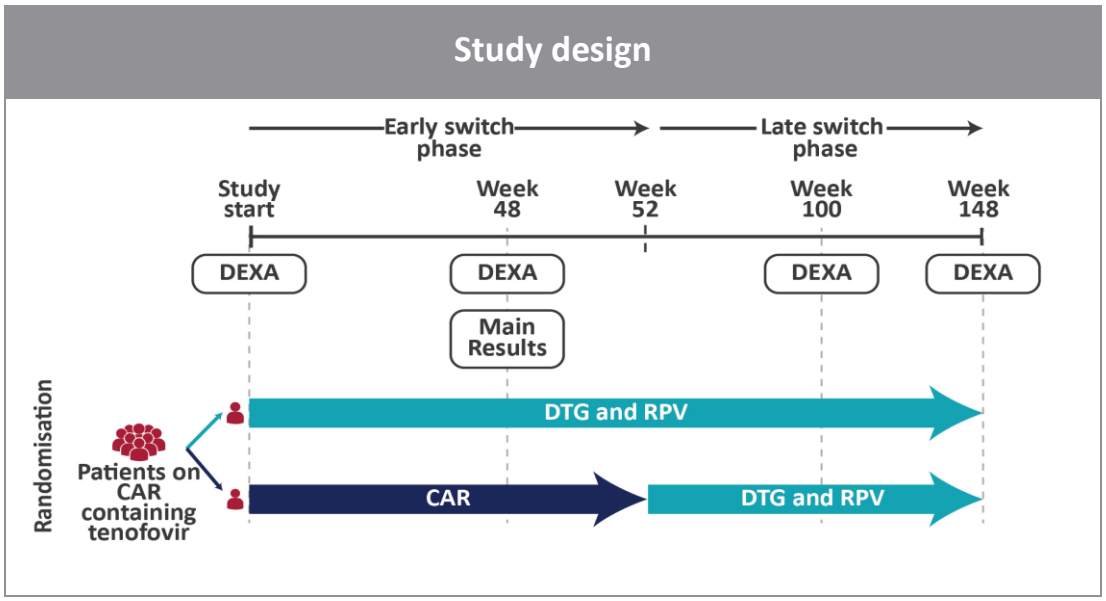
In the parent studies, patients were placed in one of the following two treatment groups by chance (randomisation):

- DTG and RPV group: At Day 1, patients switched from CAR to receive DTG and RPV.
- CAR group: Patients continued taking CAR and switched to DTG and RPV at Week 52.

No additional study medicine was given in this study.

Dual energy X-ray absorptiometry (DEXA) scans were performed on the total hip bone and the lower spine. A DEXA scan is a special type of test that measures bone mineral density, which is used to assess bone strength.

As shown in the figure below, DEXA scans were performed four times during the study.



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:

- Selected to take part in one of the parent studies (201636 or 201637) but had not received DTG and RPV before starting this study.
- Taking tenofovir as one of the medicines in their CAR.

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

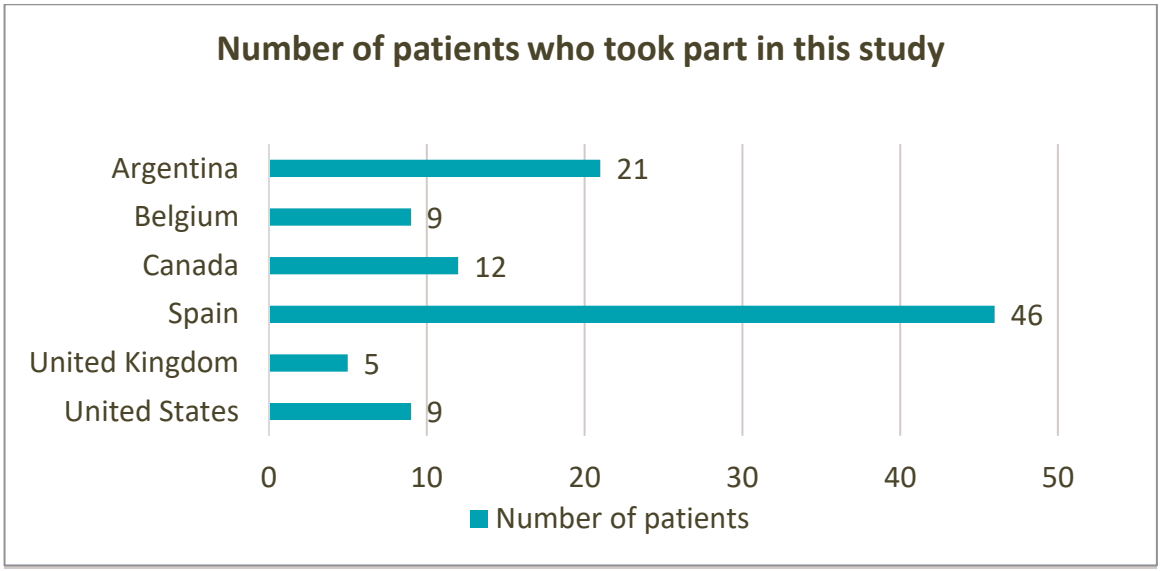
- Replacement surgery for both hips.
- Fewer than three bones in the lower spine that could be scanned to measure bone mineral density.
- Brittle bones or a history of fractures due to brittle bones.
- Vitamin D deficiency.
- Any other disease(s) or had taken any medicine(s) that the study doctor thought would affect the results of the study.

Overall, 102 patients took part in the study. The study included 49 (48%) men and 53 (52%) women. The average age was 44 years. The youngest patient was 21 years old and the oldest patient was 76 years old.

For more detailed information about the patients included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

Where was this study done?

Study sites were in six countries.



What were the main results of the study?

The main focus of the study was to compare the total hip bone mineral density of patients in both the treatment groups at Week 48. The difference between the total hip bone mineral density values at Week 48 and at study start (baseline) is called change from baseline. The percent change from baseline value could be calculated for 81 patients.

Results are shown in the table below.

Percent change from baseline in total hip bone mineral density at Week 48		
	DTG and RPV group 46 patients	**CAR group 35 patients**
Percent change from baseline	1.34%	0.05%

The percent change from baseline in total hip bone mineral density showed greater improvement in patients taking DTG and RPV compared with patients taking CAR.

More information about the study results is available in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people during a study. Study doctors record these events. A summary of adverse events can be found in the scientific results summary (a link to the summary for this study is provided at the end of this document).

In this summary, side effects (adverse reactions) refer to those events that the study doctor thinks may have been caused by the DEXA scans. The side effects in this summary may be different to those in the Informed Consent for this study or other documents related to the DEXA scans.

No side effects due to the DEXA scans were reported during the study.

Side effects that the study doctor thought may have been caused by the study medicines in the parent studies (201636[1] and 201637[2]) are reported in the plain language summaries for the parent studies posted on the ViiV Study Register (links below).

How has this study helped patients and researchers?

The main results showed that patients with HIV-1 infection taking DTG and RPV had improved bone mineral density compared with their values at study start. The bone mineral density in patients taking their CAR containing tenofovir remained similar to their values at study start. No side effects were reported in this study.

Are there plans for further studies?

Other studies of DTG and RPV in patients with HIV-1 infection have been conducted. One study is planned.

[1] https://www.viiv-studyregister.com/en/study/?id=201636
[2] https://www.viiv-studyregister.com/en/study/?id=201637

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 number associated with this study is shown below with internet link to the scientific summary.
The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organisation and Website	Study Number
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	Study 201636 NCT02429791[3]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	Study 201637 NCT02422797[4]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	Study 202094 NCT02478632[5]

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 patients with HIV-1 infection.

The content for this document was finalised by ViiV Healthcare on the 14th of December 2020. The information in this summary does not include additional information available after this date.

[3] https://clinicaltrials.gov/ct2/show/NCT02429791?term=NCT02429791&draw=2&rank=1
[4] https://clinicaltrials.gov/ct2/show/NCT02422797?term=NCT02422797&draw=2&rank=1
[5] https://clinicaltrials.gov/ct2/show/NCT02478632?term=202094&draw=2&rank=1