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 learn about the effect and safety of dolutegravir and lamivudine in participants between 12 to less than 18 years of age with newly diagnosed HIV.

Full Scientific Title: An open-label, single arm study to evaluate the week 48 efficacy and safety of a two-drug regimen of dolutegravir/lamivudine (DTG/3TC) as a fixed dose combination (FDC), in antiretroviral therapy (ART)-naive HIV-1-infected adolescents, ≥12 to <18 years of age who weigh at least 25 kg.

ViiV Healthcare Study Number: 205861

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 April 2019. Enrolment was 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 immune system. It weakens the ability to fight infections and increases the risk of developing diseases when not treated effectively. By measuring the genetic material called ribonucleic acid (RNA) levels of HIV in the blood, doctors can check the amount of HIV in the body (viral load).

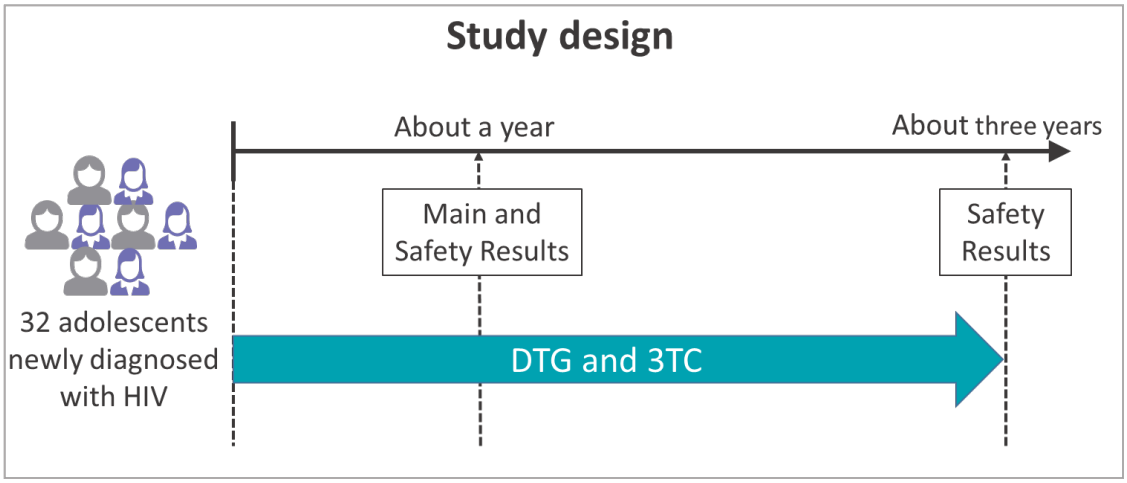
HIV medicines control the viral load by preventing it from making more virus. Researchers consider that these medicines are working well if the participants' viral load is less than 50 copies per millilitre of blood (c/mL). This means the levels of HIV in the blood is undetectable. These levels are considered to be too low to harm the immune system and are commonly tested in clinics to assess a participant's HIV status.

A combination tablet for HIV is approved in a few countries to treat adults living with HIV. Adolescents (12 to less than 18 years of age) who are newly diagnosed with HIV and have not yet received HIV treatment took part in this study. Researchers wanted to see if the same combination tablet could reduce and maintain an undetectable viral load in these participants. They also studied the safety of these medicines and compared the results from this study with results from previous studies in adults living with HIV.

Which medicines were studied?

A combination tablet of HIV medicines dolutegravir (DTG) and lamivudine (3TC) was studied.

This is an open-label study where the participants and their study doctor knew which treatment the participant received. From Day 1, all participants in this study received the combination tablet of DTG and 3TC once daily as shown in the figure below.



The participants who completed three years of treatment (Week 144) could continue receiving the study medicine until it receives approval and is available in their country.

Which participants were included in this study?

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

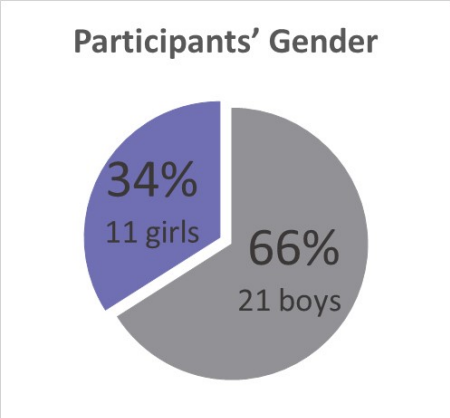
Boys and girls living with HIV were included in the study if they:

- Were 12 to less than 18 years of age.
- Weighed at least 25 kilogram.
- Had viral load between 1000 and 500,000 c/mL before starting the study.
- Had never taken HIV medicines.

Boys and girls were excluded from the study if they had:

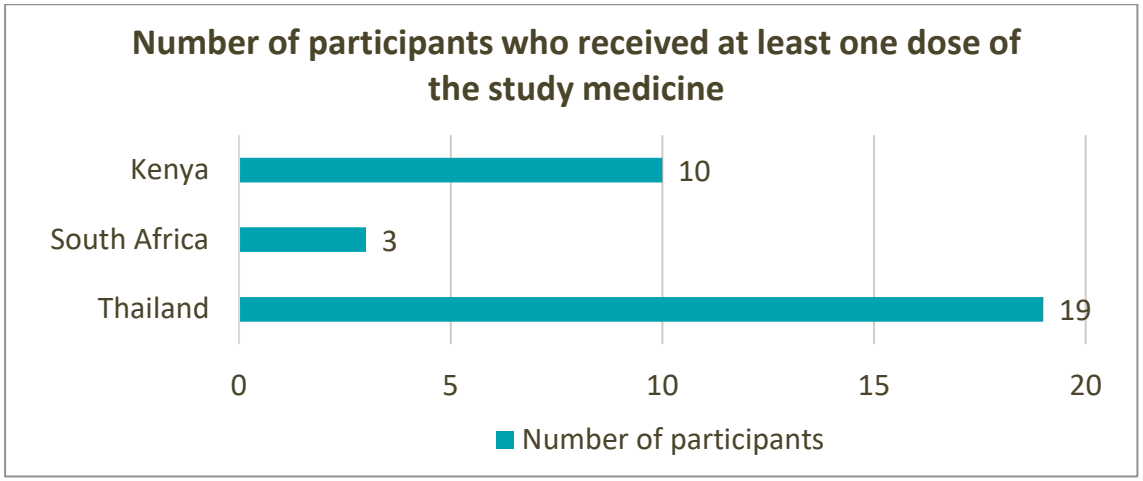
- HIV resistant (medicine no longer works) to DTG, 3TC, or similar medicines.
- Any other disease(s), abnormal blood test results, or taken any medicine(s) that the study doctor thought would affect the results of the study.

Overall, 32 participants received at least one dose of the study medicines. The average age was 16 years. The youngest participant was 13 years old and the oldest participant was 17 years old.



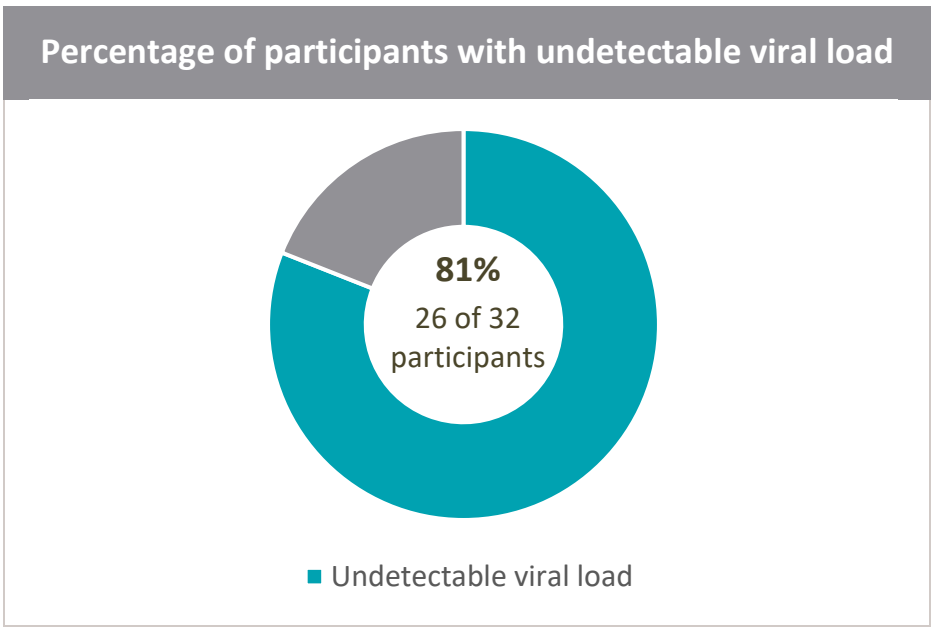
Where was this study done?

Study sites were in 3 countries.



What were the main results of the study?

Study doctors collected blood samples and measured participants' viral load. Researchers assessed the percentage of participants who had an undetectable viral load (less than 50 c/mL) after about a year (Week 48).



There were three participants who had a detectable viral load and three participants who left the study before the Week 48 visit.

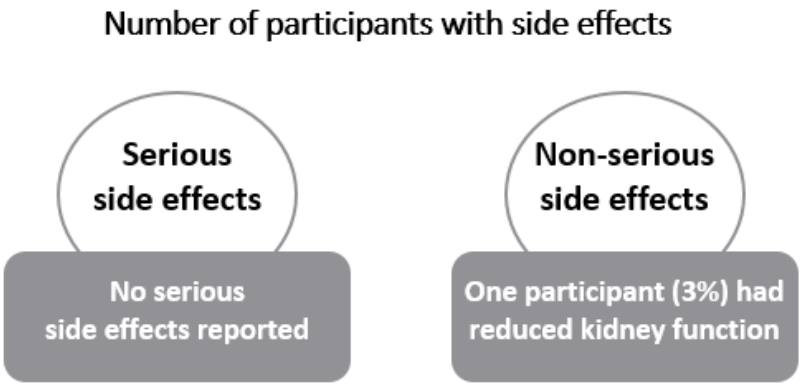
What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. In this summary, **side effects** refer to those events that the study doctor thinks may have been caused by the study medicine.

The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine. A summary of all events reported in this study may be found in the clinical results summary.

The side effects in this summary have been reported from Day 1 to about a year (Week 48).

No participant died during the study.



How has this study helped participants and researchers?

Researchers concluded that the combination tablet of DTG and 3TC had a similar response in reducing and maintaining the viral load in adolescents newly diagnosed with HIV compared with adults living with HIV. The non-serious side effect reported in this study was as expected.

Are there plans for further studies?

Other studies of DTG and 3TC in adults living with HIV have been completed. Some are ongoing or planned. No further studies of DTG and 3TC in adolescents newly diagnosed with HIV are planned at this time.

Where can I find more information about this study?

Clinical studies have unique study numbers. The unique study number associated with this study is shown below with an internet link to the scientific summary.

Organisation (Website)	Study Identifier
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03682848[1]

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. When the study is complete, final results will be available in the scientific summary.

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study.

We would like to **thank the participants** who contributed to this study. The results of this study will help answer scientific questions about treating adolescents newly diagnosed with HIV.

The content for this document was finalised by ViiV Healthcare on 31 May 2022. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/NCT03682848