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 see how well a combination of dolutegravir and lamivudine works when given right after adults are newly diagnosed with HIV.

Full Scientific Title: A Phase 3b multi-centre, open label, single arm, 52-week pilot study, evaluating the feasibility, efficacy and safety of a rapid test and treat intervention in newly diagnosed HIV-1 infected adults using a fixed dose combination of dolutegravir plus lamivudine as a first line regimen.

ViiV Healthcare Study Number: 212355

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 and where was this study done?

The study started in July 2019 and ended in October 2020. All study sites were in United States.

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 participants' viral loads reduced and remained undetectable (less than 50 copies per millilitre [c/mL]).

Adults newly diagnosed with HIV who had not received antiretroviral treatment took part in this study. Researchers wanted to see how well a combination of dolutegravir (DTG) and lamivudine (3TC) works as part of the rapid test and treat model of care. Researchers also assessed the safety of these medicines.

Which medicines were studied?

Participants with positive results from two different tests took part in the study. As part of the rapid test and treat model of care, they were provided with DTG and 3TC on Day 1, which was the same day or within 14 days of an HIV diagnosis.

On Day 1, study doctors also collected participants' blood samples for other tests, the results of which were available at a later visit. Participants with abnormal blood test results, including those who had long-term hepatitis B virus infection or resistance to DTG or 3TC, switched to a different antiretroviral treatment.

During the 52-week study, the participant and the study doctor knew which treatment the participant received.

Which participants were included in this study?

Studies have a list of requirements for participants 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 were included in the study if they:

- Were at least 18 years old.
- Had a newly confirmed diagnosis of HIV.
- Had not received antiretroviral medicines for HIV.

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

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

Overall, 131 participants received at least one dose of DTG and 3TC. The study included 121 participants (92%) who were assigned male at birth and 10 participants (8%) who were assigned female at birth. Of these, 120 participants identified as male and 11 participants identified as female. The average age was 35 years. The youngest participant was 18 years old and the oldest participant was 63 years old.

Ten participants switched to a different antiretroviral treatment during the study. Main and safety results are reported together for all 131 participants.

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

What were the main results of the study?

Study doctors collected blood samples and measured participants' viral load.

The table below shows the Week 24 and Week 48 results for participants who were still in the study and had viral load data when the results were assessed as:

- Detectable: 50 c/mL or more.
- Undetectable: Less than 50 c/mL.

Number of participants (percent) by viral load		
	Week 24 **131 participants**	**Week 48** **131 participants**
50 c/mL or more	9 (7%)	3 (2%)
Less than 50 c/mL	102 (78%)	107 (82%)

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 when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summary (a link to the summary is 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 DTG and 3TC. The side effects in this summary may be different to those in the Informed Consent for this study or other documents related to DTG and 3TC.

The side effects in this summary have been reported from Day 1 to Week 52.

No serious side effects were reported.

Non-serious side effects were reported by 10 participants (8%). The table below shows the non-serious side effects that were reported by 2% or more of participants.

Number of participants (percent) with non-serious side effects reported by 2% or more of participants	
	DTG and 3TC **131 participants**
Diarrhoea	2 (2%)
Headache	2 (2%)
Nausea	2 (2%)
Rash	2 (2%)

How has this study helped participants and researchers?

This study showed that DTG and 3TC as part of the rapid test and treat model of care are appropriate when given right after adults are newly diagnosed with HIV. Most participants had a reduced viral load that was maintained at undetectable levels. The side effects reported in this study were as expected and 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 DTG and 3TC in adults with HIV 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 number associated with this study is shown below with an 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)	NCT03945981[1]

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 participants who contributed to this study. The results of this study will help answer scientific questions about treating adults with HIV.

The content for this document was finalised by ViiV Healthcare on 9 September 2021. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/NCT03945981