WHO IS RUNNING THIS STUDY

ViiV Healthcare is a global HIV company. It develops drugs in the treatment and care of people with HIV. ViiV Healthcare is the study sponsor. ViiV Healthcare – through PPD - pays the study doctor and the institution to run this study.

GlaxoSmithKline (also called "GSK") is a healthcare company. GSK discovers and makes vaccines, medicines and other health products.

Pharmaceutical Product Development (PPD) is a contract research organization. It provides services to companies such as ViiV Healthcare and GSK to help develop drugs.

GSK and PPD are helping ViiV Healthcare to run the study.

YOUR STUDY DOCTOR

Please contact your doctor if you have any questions or concerns about study participation.

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STAT Study

A Participant's Guide

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PARTICIPATION OVERVIEW

SCREENING/ Day 1

During this visit the doctor will determine if you are eligible to participate in this study. You will have the following procedures performed:

✓Blood test ✓Physical examination

✓Urine test ✓Medical history review

✓Answering Questionnaires

✓Receive study medication

TREATMENT

If you are eligible to participate, and choose to do so, you will have regular visits to see your study doctor for up to 52 weeks. During these visits a number of procedures will occur. Some of which include:

✓Blood test ✓Review of any side effects

✓Urine test ✓Answering questionnaires

✓Vital signs ✓Receive study medication

FOLLOW-UP

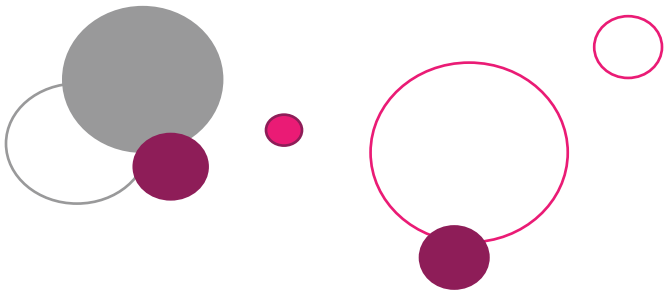
If you are having any medical problems or side effects when you finish taking the study drug, you will be asked to come in for a follow-up visit about 4 weeks after your last dose of study drug. During this visit, you have a general medical assessment and blood or urine tests if your study doctor thinks this is appropriate.

FAQs

Who has to know I am taking part of the study?
The study doctor may tell your regular doctor that you are taking part in a study. You are not required to tell your family or friends that you are taking part in this study.

How is my HIV-1 infection monitored during the study?
You will have the levels of HIV-1 in your blood tested at all study visits. If your HIV-1 level is high, you will be asked to come in for an additional blood test in 2-4 weeks.

How much time will it take to take part in this study?
Each of the 9 scheduled study visits may take about an hour to complete. This time commitment may be similar to the time required for regular doctor visits for newly diagnosed adults with HIV-1 infection.



WHY IS THIS STUDY BEING DONE?

A Phase 3b multi-center, 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 (Dovato) as a first line regimen

The purpose of this study is to evaluate the feasibility, effectiveness and safety of a rapid Test and Treat model of care over 48 weeks, using a fixed-dose combination (FDC) of dolutegravir (DTG) plus lamivudine (3TC), as your first treatment immediately, or within 14 days after initial diagnosis.

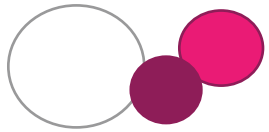
You have been asked to take part in this study because you have a new diagnosis of HIV-1 infection.

HOW DOES THIS STUDY WORK?

Overview
Everyone entering the study must have a new diagnosis of HIV-1 infection, and be willing to start treatment of their HIV infection immediately (or within 14 days of initial diagnosis).

After you are confirmed eligible to participate in the study, you will start the study treatment, the 50mg DTG + 300mg 3TC combination pill, taken once per day, with or without food, at approximately the same time of day.

What is expected of me?
You will need to visit the clinic approximately 9 times over a period of 52 weeks. Information about how the study drug that you get affects your body and your health will be collected through a number of tests, procedures and questions. The study will also look at the number of study participants who had to change their study treatment due to abnormal lab results, HIV-1 resistance mutation testing (which means that the study medication may be less effective or not effective against your HIV), or due to a side effect.



DO I HAVE TO PARTICIPATE?

Your participation is voluntary

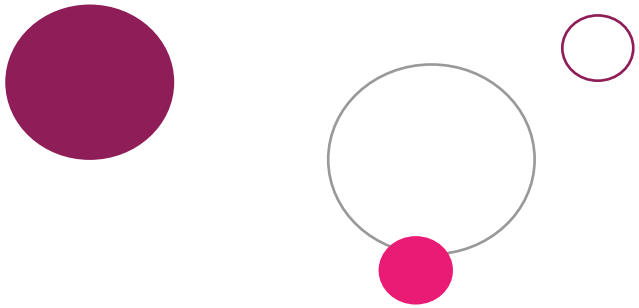
You may choose to stop taking part in the study at any time, without giving a reason. Tell the study staff if you want to stop being in the study. Your decision will not affect your medical care now or in the future. It will not involve any benefit or affect other benefits you receive outside of the study.

The study doctor will tell you as soon as possible if there is any new information that might change your decision to stay in the study.

What are my other treatment options?

You may choose to continue to get regular care from your own doctor. This may include taking other HIV drugs that are approved in the USA. Alternately, you might decide to take part in another study. The study doctor can inform you of the benefits and risks for other alternative treatment options.

You may talk with your regular doctor about your options, before you decide if you will take part in this study. The study doctor can advise you if you need more information.



ARE THERE RISKS TO PARTICIPATING?

You may have side effects while on this study. Ask the study doctor if you have any questions about the potential side effects.

Side effects may be mild or severe. The study staff/study doctor may give you medicine(s) to help lessen any side effects. Some side effects may go away as soon as you stop taking the study drug. In some cases, side effects can be serious, lasting, or may never go away.

There may be other side effects that may happen that are not known now. For example, all drugs can cause an allergic reaction in some patients.

If you do experience any side effects while on study, you should contact your study doctor immediately.

WILL IT COST ME ANYTHING TO PARTICIPATE?

As part of the study, you will receive DTG + 3TC FDC and all the study tests and procedures at no cost to you.

Before participating you should consider if this will affect any insurance you currently have or may purchase in the future, and seek advice if necessary from your insurance company.