

# A novel urine test to monitor antiretroviral treatment efficacy in HIV patients

<b>Submission date</b> 18/09/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/06/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The human immunodeficiency virus (HIV) is a type of virus known as a retrovirus. HIV attacks and weakens the immune system, making it more difficult for a sufferer to fight infections. It is a highly contagious disease, through bodily fluids such as blood, semen and vaginal fluids. There is currently no cure for HIV, but there are a range of drug treatments that can allow people who are HIV positive to lead a long and full life. Antiretroviral therapy (ART) is the standard treatment for HIV, where at least three different antiretroviral (ARV) drugs are given at the same time. This treatment is very effective at suppressing the virus and stopping the development of the disease. When a person has been on ART, the amount of HIV present in the blood (viral load) is reduced. After three to six months of treatment, the viral load should have fallen to undetectable levels (undetectable viral load). Currently, HIV is monitored using regular blood tests to check the viral load. This can cause patients a lot of discomfort however, as well as being time consuming and expensive. Recently, metabonomics analysis has shown promise in diagnosing diseases and monitoring drug therapy. This involves measuring the levels of chemicals that are left over after a drug has been broken down by the body (metabolites). The aim of this study is to see whether testing the amount of metabolites in urine is an effective way of monitoring of ART.

### Who can participate?

HIV positive adults, currently on combination antiretroviral therapy, who have had an undetectable viral load on their last two visits to the clinic.

### What does the study involve?

Ten urine samples are taken from each of the patients taking part in the study. Five of these samples are taken five days in a row, and then once every two weeks for the five remaining samples. The urine samples are then assessed in the laboratory.

### What are the possible benefits and risks of participating?

There is no direct benefit for the patients involved in the study. There are no risks of participating as the urine collection is non-invasive.

Where is the study run from?  
Wharfside clinic, St Mary's Hospital (UK)

When is the study starting and how long is it expected to run for?  
October 2015 to December 2020 (updated 11/06/2019, previously: April 2016)

Who is funding the study?  
1. Imperial NIHR Biomedical Research Centre (UK)  
2. Institute for Translational Medicine and Therapeutics (UK)

Who is the main contact?  
Dr Xinzhu Wang  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Optimising metabonomic analysis to monitor combination antiretroviral therapy efficacy in urine samples from HIV patients

**Study objectives**  
The aim of this study is to determine which platform builds the best model for assessing patient stability over a short to moderate period of time.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

NRES Committee London - Bromley, 04/09/2015, ref: 15/LO/1584

**Study design**

Single-centre observational trial

**Primary study design**

Observational

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Human immunodeficiency virus (HIV)

**Interventions**

Ten sequential samples are taken from each patient over the course of 10 weeks. The intra-patient variability is determined in the metabolic profiling of patients who are stable on ART with undetectable viral load over a short-med period of time using using nuclear magnetic resonance spectroscopy and liquid chromatography mass spectrometry.

**Intervention Type**

Other

**Primary outcome(s)**

Urine metabonomic profiles will be measured using proton nuclear magnetic resonance spectroscopy and liquid chromatography mass spectrometry on days 1, 2, 3, 4, 5, 15, 29, 43, 57 and 71.

**Key secondary outcome(s)**

N/A

**Completion date**

31/12/2020

**Eligibility****Key inclusion criteria**

1. At least 18 years of age
2. HIV positive
3. Currently taking combination antiretroviral therapy
4. Two undetectable viral loads measured in the most recent visits

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Persons who lack the capacity to consent

**Date of first enrolment**

01/10/2015

**Date of final enrolment**

01/04/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Wharfside clinic**

St Mary's Hospital

Praed Street

London

United Kingdom

W2 1NY

## **Sponsor information**

**Organisation**

Imperial College London

**ROR**

<https://ror.org/041kmwe10>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Imperial NIHR Biomedical Research Centre

**Funder Name**

Institute for Translational Medicine and Therapeutics

**Alternative Name(s)**

ITMAT

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United States of America

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Stored in repository

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No