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

Submission date
18/09/2015

Recruitment status
No longer recruiting

Registration date
28/10/2015

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 supressing 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
N/A

Overall study start date
01/10/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre
Wharfside clinic
St Mary's Hospital
Praed Street

London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London

Sponsor details
Joint Research Compliance Office
Imperial College London & Imperial College Healthcare NHS Trust
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Sponsor type
University/education

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

Publication and dissemination plan
Publication in a peer-reviewed journal.

Intention to publish date
31/12/2020

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?
HRA research summary			28/06/2023	No	No