ISRCTN12803987 https://doi.org/10.1186/ISRCTN12803987

Performance evaluation of a point-of-care whole blood viral load test (SAMBA II HIV-1 Semi-Q Whole Blood) to optimise HIV treatment

Submission date
31/08/2016

Recruitment status
No longer recruiting

Registration date
02/09/2016

Overall study status
Completed

Last Edited
25/09/2018

Condition category
Infections and Infestations

[X] 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 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. Routinely monitoring the viral load (VL) through regular blood testing is a vital part of this treatment strategy, as it is able to identify treatment failure so the drugs used can be changed. Current HIV VL tests are limited to centralised laboratories, as they require high organization and trained personnel. HIV patients living outside of major cities in developing countries often do not have access to VL testing. Even when VL testing is available, there are often delays in obtaining test results or loss of samples during shipment, leading to high loss to follow-up. Point-of-care VL testing (testing samples there and then) in lower healthcare facilities may overcome these limitations, improving patient outcomes and preventing spread of the disease. The aim of this study is to find out whether point-of-care HIV viral load testing with SAMBA II HIV-1 Whole Blood SemiQ is as accurate as centralised HIV viral load testing.

Who can participate?
HIV positive adults

What does the study involve?
HIV positive patients who attend the clinics for routine VL monitoring are invited to provide an additional blood sample for VL testing with SAMBA II HIV-1 Whole Blood Semi-Q at the same time as they provide blood samples for their routine VL testing. The clinic processes the blood for the routine HIV VL test and informs patients of the results according to normal clinic procedures. The additional blood sample is tested with SAMBA II HIV-1 Whole Blood Semi-Q, but

patients are not given the results. The results from the two tests are then compared in order to find out whether the point-of-care testing is as accurate as the normal procedure.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved to participants taking part in this study.

Where is the study run from?
The study will be conducted in 4 countries: United Kingdom, Ukraine, Cameroon and Uganda. There will be one clinic in each of the United Kingdom (Central Middlesex Hospital, London) and Ukraine (National Medical Academy, Kiev) and up to 6 rural lower healthcare clinics in Uganda and Cameroon.

When is the study starting and how long is it expected to run for?
June 2016 to August 2017

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Sarah Oakley-Mudge

Contact information

Type(s)
Scientific

Contact name
Dr Allyson Ritchie

Contact details
-
Cambridge
United Kingdom
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC SAMBA II WB Semi-Q

Study information

Scientific Title

Comparing a new point-of-care whole blood viral load test (SAMBA II HIV-1 Whole Blood Semi-Q) to a gold standard test in HIV positive patients in the UK, Ukraine and Africa: A diagnostic accuracy study

Study objectives
Point-of-care HIV viral load testing with SAMBA II HIV-1 Whole Blood SemiQ is concordant with Gold Standard centralised HIV viral load testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre non-randomised diagnostic accuracy study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Diagnostic

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
HIV

Interventions
HIV positive patients who attend the clinic for routine VL monitoring will be invited to provide an additional blood sample for VL testing with SAMBA II HIV-1 Whole Blood Semi-Q. Trained clinic staff will collect venous blood required for the routine clinic tests together with one additional blood sample (either venous or capillary). The clinic will process the blood for the routine HIV VL test and inform patients of the results according to normal clinic procedures. The additional blood sample will be tested with SAMBA II HIV-1 Whole Blood Semi-Q. Patients will not receive the results from the SAMBA II HIV-1 Whole Blood Semi-Q assay.
There is no follow up for participants.

Intervention Type
Device

Primary outcome measure

Diagnostic accuracy of the SAMBA HIV-1 Whole Blood Semi-Q test determined by concordance to the Gold Standard HIV viral load test (within 0.3 log10 copies/ml).

Secondary outcome measures
Association between collected clinical covariates (age, country and gender) with the concordance between test is determined using the Wald test statistic of parameter associated with clinical covariate in logistic regression with concordance as outcome.

Overall study start date
01/06/2016

Completion date
15/10/2018

Eligibility

Key inclusion criteria
1. HIV sero-positive
2. Aged 18 years and over
3. Able to understand patient information sheet and consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2300

Key exclusion criteria
1.Below 18 years old or unable to understand forms or procedure
2. Pregnant women
3. Co-infection with active TB

Date of first enrolment
01/11/2016

Date of final enrolment
02/06/2017

Locations

Countries of recruitment

Cameroon

England

Uganda

Ukraine

United Kingdom

Study participating centre
Central Middlesex Hospital
Acton Lane
Park Royal
London
United Kingdom
NW10 7NS

Study participating centre
National Academy of Postgraduate Education
Ukraine
04112

Study participating centre
Ministry of Health
Uganda
P.O. Box 7272

Study participating centre
Global Health Solutions
Cameroon
Box Limbe L

Sponsor information

Organisation
Diagnostics for the Real World (Europe) Ltd.

Sponsor details

Suite 8
Science Village
Chesterford Research Park
Cambridge
United Kingdom
CB10 1XL

Sponsor type
Industry

ROR
https://ror.org/04e2ayg86

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available