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PIMA point-of-care CD4 testing and its impact on ART initiation, linkage to care and retention

Submission date
24/05/2018

Recruitment status
No longer recruiting

Registration date
11/06/2018

Overall study status
Completed

Last Edited
10/02/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
South Africa has the greatest burden of HIV in the world with 6.4 million people infected. Immunity is assessed for these patients by CD4 count testing and the result used to determine eligibility for antiretroviral treatment (ART) and various other treatments and interventions. Point-of-care testing allows on-site CD4 testing by finger prick blood sample and gives the result in 20 min. Currently South Africa uses central CD4 testing where the specimens are transported to a few central laboratories with results taking days to weeks to come back to the clinic and requiring extra visits for patients. Patients may become lost to follow up if they do not return. This study introduces PIMA CD4 testing into a high burden primary health care clinic on certain randomly allocated weeks and compares it to conventional central laboratory testing done on the other weeks. This allows a comparison of the point-of-care CD4 test to the central testing to see the effect it has on how many patients commence ART, how long it takes them to start treatment and whether the patients remain in care. As all patients receive the same counselling by the same staff and answer the same questionnaire it helps to keep the two groups as similar as possible to measure the changes accurately.

Who can participate?
Adults aged over 18 who are HIV positive and present for CD4 testing at the clinic. They may not be pregnant or on ART

What does the study involve?
The week time periods are randomly allocated so on some weeks all patients are tested with the point-of-care CD4 PIMA test where they give a finger prick sample of blood and get the result back in 20 min. They are counselled before and after the test and complete a questionnaire with the counsellors. If they are having other bloods taken a venous sample is used so as not to prick them twice. On the other weeks patients have the same counselling and answer the questionnaire but their blood is sent for central laboratory testing as usually happens and they are asked to come back for their result. All patients continue through the clinic for their routine care and follow up.

What are the possible benefits and risks of participating?
The benefits to the patients who receive PIMA testing is they can get their results on the same

day before leaving the clinic and know what their treatment plan is. Both groups have the benefit of counselling by the study staff and if they are sick the study doctor can see them so they don't have to wait in the clinic queues. There are no additional risks by participating in the study – just the symptoms from taking blood that would happen off the study.

Where is the study run from?
Lancers Road Clinic (South Africa)

When is the study starting and how long is it expected to run for?
August 2014 to July 2018

Who is funding the study?
The study is funded by Alere who are supplying the machines and cartridges for the POC testing and the University of KwaZulu Natal and the Medical Research Council are providing the additional funding for staff and supplies

Who is the main contact?
Dr Elizabeth Spooner
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BF/480/14

Study information

Scientific Title
Testing the operational role of PIMA point-of-care (POC) CD4+ T cell testing and its impact on ART initiation, linkage to care, and retention in care in a Primary Health Care clinic in Durban, South Africa

Study objectives
Primary hypothesis:
PIMA POC CD4 testing improves the rate of ART initiation (within 3 months of testing) with same day provision of results versus the routine standard of care NHLS (National Health Laboratory Service) CD4 monitoring

Secondary hypotheses:
1. PIMA POC CD4 testing decreases the time to initiate ART treatment for those eligible for ARV therapy compared to the standard NHLS testing
2. There is a significant improvement in linkage to care for non-ART patients who receive PIMA POC CD4 results vs NHLS CD4 results as measured by their return for CD4 testing within 6-8 months of previous test

Ethics approval required
Old ethics approval format

Ethics approval(s)
Biomedical Research Ethics Committee of the University of KwaZulu-Natal, 23/02/2015, ref: BF /480/14

Study design
Effectiveness implementation hybrid interventional study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
HIV CD4 cell testing for care and treatment in primary health care

Interventions
PIMA point-of-care CD4 testing as the intervention with conventional laboratory based CD4 testing at the National Health Laboratory (Beckman Coulter) as the control. The time periods (weeks) are randomised for either test method so that patients are assigned to either POC testing or NHLS testing for each week, creating 2 clusters. For POC testing a 25 microliter finger prick sample is placed into a cartridge with is placed in the analyser and gives a result in 20 minutes. The NHLS specimen uses a 5 ml venous sample which is sent to the central laboratory with the result reaching the clinic in 3-4 working days. All participants receive the same counselling and complete the same socio-demographic questionnaire.

Intervention Type
Other

Primary outcome measure
The percentage improvement in the rate of ART initiation (within 3 months of testing) using PIMA POC CD4 testing with same day provision of results versus the routine standard of care NHLS CD4 monitoring

Secondary outcome measures
1. The difference in time to initiate ART treatment for those eligible for ARV therapy in the implementation PIMA POC group compared to the standard NHLS group
2. The linkage to care for non-ART patients who receive PIMA POC CD4 results vs NHLS CD4 results as measured by their return for CD4 testing within 6-8 months of previous test
3. The impact of certain variables (disclosure, family support and family members engagement in care) on a patient's linkage to care
4. The benefit if any to the patient of receiving same day results with respect to time and cost savings

Overall study start date
01/08/2014

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. HIV positive adults not on ART
2. Patients willing to provide informed consent for samples to be tested

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

600 patients across 2 clusters with approximately 300 in each cluster

Total final enrolment
603

Key exclusion criteria
1. HIV negative patients
2. Children under 18 years old
3. Pregnant women
4. Patients on ART

Date of first enrolment
13/04/2015

Date of final enrolment
06/10/2015

Locations

Countries of recruitment
South Africa

Study participating centre
Lancers Road Clinic
90 Lancers Road
Durban
South Africa
4001

Sponsor information

Organisation
University of KwaZulu-Natal

Sponsor details
Department of Paediatrics and Child Health
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Sponsor type
University/education

ROR

https://ror.org/04qzfn040

Funder(s)

Funder type
Industry

Funder Name
Alere South Africa

Funder Name
South African Medical Research Council

Alternative Name(s)
SAMRC

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
South Africa

Results and Publications

Publication and dissemination plan
Intend to publish in 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/02/2022	10/02/2022	Yes	No