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Testing the specificity, operational feasibility and acceptability of point-of-care (POC) HIV testing compared to conventional laboratory testing for early infant diagnosis (EID) in Durban, South Africa

Submission date
13/12/2017

Recruitment status
No longer recruiting

Registration date
09/01/2018

Overall study status
Completed

Last Edited
23/11/2020

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
The World Health Organization (WHO) says Universal Health Coverage is achieved when everybody receives the quality health services needed without suffering financial hardship. The WHO also promotes people-centered healthcare that is best for patients, health care workers and the community.
To this end, point-of-care (POC) testing is when patient specimens are tested quickly, allowing healthcare workers to use the result there and then to give the patient the right care and treatment. There are many new POC tests being developed that can help both patients and healthcare workers. HIV is an incurable sexually transmitted disease and may be transmitted from a mother to her child in the womb, during birth and through breast milk. HIV causes disease and suffering worldwide but especially in Africa where the most people with HIV live. Antiretroviral treatment (ART) is given to people who are HIV positive to control the virus and help them to stay healthy. If a mother takes ART during pregnancy and breastfeeding her child is protected from getting HIV from her. Before ART availability, 30 in 100 babies born to HIV positive mothers would get HIV. Now only 1 or 2 in 100 are getting HIV as ART is given to all pregnant mothers. However, all babies of HIV-positive mothers still need to be tested for HIV. Babies who get HIV do best when started on ART as soon as possible after they become infected. Without ART half will die in the first year of life and many before 3 months of age. It is also reassuring for a mother to know her babies result even if it is negative. Babies cannot be tested with the same tests as adults as these test for HIV antibodies which are passed from mothers to their babies, so the babies would all test falsely positive. Babies have to have expensive tests that detect the actual HIV virus. Presently in South Africa, the baby’s blood is sent to a central laboratory using a dried blood spot (DBS) and the HIV result is available after a few days. The WHO has approved some rapid HIV tests that can give the babies' HIV result in 1-2 hours, which means positive babies can be started on treatment immediately. Mothers of negative babies can know that their baby is negative there and then. South Africa has by far the

highest number of people with HIV in the world and Durban, where the study is conducted, has the highest HIV prevalence (4 out of 10 pregnant mothers have HIV). The aim of this study is to use a POC HIV test for babies of HIV-positive mothers and determine the accuracy of the POC test, if mothers and healthcare workers like it, and if it is able to be introduced into a hospital and clinic.

Who can participate?
Mothers with HIV are invited to allow their babies to participate in the study

What does the study involve?
Babies are tested for HIV using the Alereq Detect HIV test. One drop of the baby's blood from a heel-prick goes into a cartridge and into a machine, which gives the result in 50 minutes. Testing is performed during office hours while study staff are present. Routine dry blood spot tests are still done on each baby where 3-5 wells are filled with blood on a card and sent to the laboratory at Inkosi Albert Luthuli Hospital. This result is put onto a central computer register and can be collected at the hospital or clinic in 1-2 weeks. This is so the tests can be compared for accuracy. Study counselors also ask the mothers some questions about their background and how they feel about the test. The hospital and clinic staff are trained how to use the Alereq machine and encouraged to do the new POC test. They also complete a questionnaire at the end to understand how they found the testing. Study staff are always present to get consent from patients and administer the study questionnaire. They also perform the DBS testing so as not to increase the workload of the healthcare workers.

What are the possible benefits and risks of participating?
The benefit of participating is that mothers get the baby's HIV result on the same day. There is a chance that the POC test may give an error, which means it is repeated, but mothers still get the result as soon as possible on the same day. The heel-prick may cause a little discomfort to the baby and some bruising, as may occur if babies just had the routine DBS test. If a baby is positive mothers are counselled, supported and cared for and the baby can be started on ART straight away with the paediatricians at the hospital or clinic doctors at the clinic. Staff can ensure mothers receive adequate counseling and help with the ART for the baby before they go home. The study staff includes a doctor and an HIV/breastfeeding counselor who can give mothers any additional advice and counseling if required.

Where is the study run from?
Addington Hospital and Lancers Road Clinic in Durban (South Africa)

When is the study starting and how long is it expected to run for?
August 2015 to January 2018

Who is funding the study?
The South African Medical Research Council (SAMRC) (South Africa)

Who is the main contact?
Dr Elizabeth Spooner
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KZ_2015RP43_313

Study information

Scientific Title
Testing the specificity, operational feasibility and acceptability of point-of-care (POC) HIV testing compared to conventional laboratory testing for early infant diagnosis (EID) in Durban, South Africa

Acronym
EID study

Study objectives
Point of care testing for early infant diagnosis is accurate, acceptable and feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Biomedical Research Ethics Committee of the University of Kwa-Zulu Natal, 05/04/2016, ref: BF461/15
2. Kwa-Zulu Natal Department of Health, Health Research and Knowledge Management Directorate, 14/03/2016, ref: KZ_2015RP43_313

Study design
Implementation study observing the accuracy, feasibility and acceptability of point-of-care HIV testing on infants at birth in a hospital and at follow up in a primary health clinic compared to laboratory based testing performed on the same infants at the same time

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 to request a patient information sheet

Health condition(s) or problem(s) studied
HIV-exposed infants and their mothers

Interventions
Point-of-care HIV PCR testing is performed on HIV exposed infants around birth in Addington hospital and at Lancers rd primary health care clinic using the Alere™q HIV-1/2 Detect test which is performed from a 25µl drop of blood into a test cartridge and processed in the Alereq machine in 50min. This is compared with the standard of care dry-blood-spot specimen which is sent to the central National Health Laboratory Services laboratory for testing with the Roche COBAS Ampliprep/COBAS Taqman (CAP/CTM) HIV-1 Qualitative test v2.0. Questionnaires are administered to the mothers and healthcare workers.

Intervention Type
Other

Primary outcome measure
Sensitivity and specificity of the point of care testing compared to the standard of care laboratory testing, measured at the time of testing

Secondary outcome measures
Acceptability of POC testing to mothers and health care workers and operational feasibility of POC testing in both settings, measured using a quantitative/qualitative questionnaire that the mothers are asked at an interview on the day of testing with open and closed ended questions. The staff were interviewed after study completion and a quantitative/qualitative questionnaire with open and closed ended questions is completed at one timepoint.

Overall study start date
01/08/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Infants delivered to HIV infected mothers at Addington hospital
2. Infants presenting for HIV PCR testing at Lancers rd clinic

Participant type(s)
Mixed

Age group
Neonate

Sex
Both

Target number of participants
452 infants

Total final enrolment
440

Key exclusion criteria
1. HIV unexposed infants
2. Infants whose mothers do not give written, informed consent to participate in the study

Date of first enrolment
07/02/2017

Date of final enrolment
22/08/2017

Locations

Countries of recruitment
South Africa

Study participating centre
Addington Hospital
Durban
South Africa
4001

Study participating centre
Lancers Road Primary Healthcare Clinic
Durban
South Africa
4001

Sponsor information

Organisation
University of KwaZulu-Natal, School of Clinical Medicine, Department of Paediatrics and Child Health

Sponsor details
4th Floor, Main Building
Nelson R Mandela School of Medicine Campus
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Sponsor type
University/education

ROR
https://ror.org/04qzfn040

Funder(s)

Funder type
Research council

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
To be submitted to BMC Public Health in January 2018 with the intention to publish in early 2018.

Intention to publish date
01/02/2018

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	results	11/06/2019	23/11/2020	Yes	No