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Development of a program to monitor patients who were started on HIV treatment on the same day of HIV diagnosis

Submission date
22/01/2025

Recruitment status
No longer recruiting

Registration date
03/04/2025

Overall study status
Completed

Last Edited
03/04/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The South African government wants to improve HIV treatment and achieve global targets. One way to do this is by starting patients on antiretroviral therapy (ART) on the same day they're diagnosed with HIV. This approach is called same-day initiation (SDI). Research shows that starting ART early reduces illness, death, and the spread of HIV. It also boosts patients' hope and optimism. However, putting SDI into practice is challenging due to various obstacles. Some of the challenges include structural barriers such as healthcare system issues, like laboratory result delays; attitudes such as patients' and healthcare providers' attitudes toward SDI; and additional challenges in developing countries such as substance abuse, housing instability, and managing clinical symptoms. Although South Africa has adopted SDI, there are concerns about whether patients stay in treatment and how effective the treatment is. This study aims to create a comprehensive plan (standard operating procedure) to:
1. Monitor how well SDI is implemented.
2. Measure the outcomes of treatment.
By doing so, the study hopes to improve the effectiveness of SDI in South Africa.

Who can participate?
All newly diagnosed people aged 12 years and over living with HIV

What does the study involve?
Participants are randomly allocated to one of two groups, namely the intervention group and the control group. The intervention group would receive the interventions aimed at improving treatment outcomes, while the control group would use the normal protocol which does not involve new interventions. Lastly, this study involves the collection of blood, home visits, and social worker involvement among patients in the intervention group.

What are the possible benefits and risks of participating?
The participants may benefit directly from this study due to improved treatment outcomes

(adherence, viral load suppression and prevention of HIV-related deaths). Secondly, patients have an opportunity to see a social worker, assigned to a treatment advisor, and have their treatment delivered to their homes. There are no risks in participating in this study.

Where is the study run from?
This study was run in the O.R. Tambo district, Eastern Cape, South Africa. The study was conducted at three healthcare clinics, namely, Mthatha Gateway Clinic, Tsolo Clinic, and Flagstaff Clinic.

When is the study starting and how long is it expected to run for?
The study was conducted (begin data collection) from 09 January 2023 to 16 August 2023. This study was expected and ran for six months. However, the study plan was proposed on 06/08 /2021.

Who is funding the study?
This study was supported by the Chemical Industries Education and Training Authority (CHIETA) and the Strategic Health Innovation Partnerships (SHIP) of the Medical Research Council (MRC), funding attributed to Prof. Eugene Jamot Ndebia.

Who is the main contact?
For the study: Siyakudumisa Nontamo, siyakudumisanontamo86@gmail.com and 206607687@mywsu.ac.za
For funding: Professor Eugen Ndebia endebia@wsu.ac.za

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Developing a Standard Operating Procedure for monitoring same-day initiation of antiretroviral therapy among newly diagnosed persons living with HIV in South Africa

Study objectives
By and large, when carefully measured and monitored, same-day antiretroviral therapy (ART) initiation improves treatment adherence, retention to care, and viral load suppression. A procedure to measure and monitor same-day ART initiation will be associated with positive treatment outcomes. As a result, if developed and implemented, positive treatment outcomes will flourish even further in South Africa. Therefore, the HIV care continuum will be optimized, and the 959595 UNAIDS strategy will be achieved by 2024. Subsequently, the Millennium Development Goal (MDG) that aims to achieve an ambition of free HIV generation' by 2030 is to be achieved, and life expectancy will further improve.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/09/2022, Walter Sisulu University Faculty of Health Sciences Research Ethics and Biosafety Committee (Walter Sisulu University, NMD Campus, Private Bag X1, Mthatha, 5099, South Africa; +27 (0)475022100; fhs@wsu.ac.za), ref: 027/2022

Study design
Multicenter interventional unblinded randomized controlled trials

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Improving adherence to HIV treatment among newly HIV-diagnosed patients

Interventions
Following the patients' written informed permission, the researcher conducted a screening evaluation to assess the study exclusion criteria. Eligible participants were then enrolled and randomly assigned on the same day of HIV testing. A computer-generated random-number list was used to randomly assign participants to either standard ART or same-day ART initiation in a 1:1 ratio, with allocation concealment. Participants were enrolled and divided into study groups by the researcher. However, participants, site personnel, and the study supervisor were not blinded to the group assignments.

After randomization:
1. Standard group: Received ART initiation as per national guidelines, with follow-up on Day 28
2. Intervention group: Received additional support, including:
2.1. Assignment to patient navigator after starting treatment
2.2. Day 5: Nurse support (blood result interpretation, side effect management, counseling)
2.3. Day 14: Social worker support (counseling, disclosure support, needs assessment, opportunistic infection evaluation)

The duration of the interventions was 6 months from the date the participant was enrolled in the study.

Intervention Type
Mixed

Primary outcome measure
Retention in care is defined as maintaining an HIV-1 RNA level <50 copies/ml 6 months following HIV testing. This outcome was measured at baseline and month 6 using the whole blood that would measure HIV-1 RNA level (viral load)

Secondary outcome measures
1. Retention in care with HIV-1 RNA <1,000 copies/mL at 6 months post-testing, which was also measured from baseline and at month 6

2. Adherence is measured using pharmacy refill records at months 1, 2, 3, 4, 5, and 6
3. Loss to follow-up measured using patient charts and phone calls at 6 months into treatment
4. Mortality rate was measured using phone calls to verify from the family members and the clinic file at months 1, 2, 3, 4, 5, and 6

Overall study start date
06/08/2021

Completion date
16/08/2023

Eligibility

Key inclusion criteria
1. All patients above 18 years are eligible for ART on the same day as HIV testing services (HTS) (same-day initiation)
2. Patients whose status is known but who have never been initiated on ART
3. Adolescents from 12 years after the completion of the HIV disclosure process in accompaniment of the parent or caregiver
4. Stable mental health patients deemed fit to be initiated on ART
All patients whose permanent and temporary addresses are known and reachable for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
12 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
130

Total final enrolment
142

Key exclusion criteria
1. Symptomatic client who does not meet the criteria of same-day ART initiation
2. Active mental health condition
3. Clients below the age of 12 years
4. Antenatal clients enrolled in the prevention of mother-to-child transmission program
5. Known HIV-positive client who was once initiated on treatment and defaulted

6. TB co-infected client
7. A newly HIV-positive person who is likely to seek a transfer to unreachable locations during the study period.

Date of first enrolment
03/01/2023

Date of final enrolment
17/02/2023

Locations

Countries of recruitment
South Africa

Study participating centre
Tsolo Clinic
Dr Malizo Mpehle Hospital Road, main road, Tsolo, 5170
Mthatha
South Africa
5099

Study participating centre
Flagstaff Clinic
76 Main Street
Flagstaff
South Africa
4810

Study participating centre
Mthatha Gateway Clinic
Mthatha General Hospital
71 Nelson Mandela Drive
Mthatha
South Africa
5099

Sponsor information

Organisation
South African Medical Research Council

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Sponsor type
Research council

Website
http://www.mrc.ac.za/

ROR
https://ror.org/05q60vz69

Funder(s)

Funder type
Other

Funder Name
Chemical Industries Education and Training Authority (CHIETA)

Funder Name
Strategic Health Innovation Partnerships (SHIP) of the Medical Research Council (MRC)

Results and Publications

Publication and dissemination plan
Publication plan:
1. Peer-reviewed articles: Publish at least 2-3 articles in high-impact, peer-reviewed journals, such as:
1.1. Journal of Acquired Immune Deficiency Syndromes (JAIDS)
1.2. AIDS
1.3. PLOS Medicine
2. Conference presentations: Present research findings at international conferences, such as:
2.1. International AIDS Conference
2.2. Conference on Retroviruses and Opportunistic Infections (CROI)
3. Research reports: Publish detailed research reports on the study's methodology, results, and conclusions.

Dissemination plan:
1. Stakeholder engagement: Share research findings with stakeholders, including:
1.1. Ministry of Health
1.2. National AIDS Program
1.3. Healthcare providers
1.4. Community-based organizations
2. Policy briefs: Develop policy briefs to inform policy decisions and guide program implementation.
3. Social media and online platforms: Utilize social media and online platforms to disseminate research findings to a broader audience.
4. Community outreach: Engage with local communities to share research findings and promote the adoption of evidence-based practices.
5. Capacity building: Provide training and capacity-building workshops for healthcare providers and researchers to enhance their skills in implementing evidence-based practices.

Timeline
Months: January-March 2025: Submit manuscripts for publication and present research findings at conferences
Months April-June 2025: Disseminate research findings to stakeholders and develop policy briefs
Months: July-December 2025: Continue dissemination and capacity-building activities

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Siyakudumisa Nontamo (siyakudumisanontamo86@gmail.com) and Professor Eugene Ndebia (endebia@wsu.ac.za)

IPD sharing plan summary
Available on request