Clinical trials design and methodology

PO - (8447) - ROBUST CLINICAL TRIALS ARE NOT ENOUGH: OVERCOMING OPERATIONAL CHALLENGES FOR IMPLEMENTING REMSTART INTERVENTION PACKAGE (TRIP STUDY) INTO ROUTINE PRACTICE.

Kivuyo, Sokoine (Tanzania); Erick, Frank (Tanzania); Loyse, Angela (United Kingdom); Jaffar, Shabbar (United Kingdom); Mfinanga, Gofrey (Tanzania)

1 - National Institute For Medical Research-Muhimbili Centre; 2 - ST Georges University of London; 3 - Liverpool School of Tropical Medicine

Background: The REMSTART trial identified an effective package (cryptococcal antigen (CrAg) screening and enhanced antiretroviral therapy (ART) adherence support) that reduced all-cause mortality in advanced HIV (CD4 ≤ 200 cells/mm³) by 28% compared to standard of care. The introduction of this package at clinic level has been necessary to impact routine care practices in Tanzania.

Methods: The TRIP study is cluster-randomised. The intervention package was implemented in 16 routine care facilities (early arm) whilst 8 facilities continued with standard of care (deferred arm). At the end of 12 months follow-up, the intervention was implemented in the deferred facilities. The primary end point is all-cause mortality at 1 year.

Results: Implementation of the REMSTART intervention into routine care services has highlighted the following challenges:

1) Baseline CD4 testing: Half (4/8) rural facilities had no CD4 machines and in a further 3/8 there was a lack of reagents needed for CD4 testing. Clinical staging has replaced inclusion criterion where CD4 testing is not available.

2) Heavy routine care staff workload: Regular discussion with policy makers and workshops enhanced the take up of the package.

3) Timing of ART: Ministry of Health have updated national guidelines to include the package and delaying ART by 2 weeks in CrAg positives.

Conclusion: It has proven essential to engage with policy makers and programme managers from the outset– within the REMSTART trial itself –followed by the implementation TRIP study. Ministry of Health has now changed the national HIV guidelines to include the REMSTART package and develop training modules for CrAg screening in all regional hospitals. The TRIP study has revealed key issues that must be addressed to allow scaling up of interventions.