



## **Baseline characteristics and long term clinical outcomes of patients using Malawi's new first line antiretroviral regimen at Lighthouse: The Lighthouse Tenofovir Cohort LighTen**

### **Background**

In July 2013 the Malawian National HIV Programme introduced a new first line regimen for HIV antiretroviral therapy. In line with WHO recommendations this regimen consists of Tenofovir (TDF), a potent antiretroviral compound with antiviral effects against both HIV and Hepatitis B virus (HBV), in a fixed dose combination with Lamivudine (3TC) and Efavirenz (EFV). All patients initiating ART since have been started using this regimen and patients already on ART have been switched. 3TC and EFV have been used widely since the inception of the Malawian ART Programme while TDF was only being used as an alternative first line agent for patients unable to tolerate other NRTI's or as second line agent. Although, generally well tolerated, use of TDF is known to result in a reduction in renal glomerular filtration. In addition, in a small minority of patients it has been associated with Acute Tubular Necrosis, resulting in acute renal failure. Despite these potential risks, the National ART Programme does not include renal function screening at initiation or during the course of treatment. Currently, the number of patients initiating ART in Malawi who suffer from pre-existing renal damage, either associated with or independent from their HIV status, is unknown. Although recent retrospective data from Zambia suggest that the TDF induced renal damage is low, there is a need to establish a Malawian cohort of patients who will be prospectively monitored very closely with regard to multiple parameters, including renal function. The cohort study will also identify patients with active HBV infection who will have a significant additional benefit from the new treatment and look for existing comorbidities such as Hypertension and Diabetes.

### **Study Site and Consortium**

The study will be conducted at the Lighthouse Clinic in Lilongwe Malawi which cares for more than 20.000 patients on ART. [www.mwlighthouse.org](http://www.mwlighthouse.org)

The study will be cooperatively conducted by the Lighthouse and its partners

- the Institute of Public Health University Heidelberg Germany
- the University Clinic Cologne

Medical Clinic I, Infectious Disease Department and Clinic for Gastroenterology and Hepatology

### **Aim and Objectives**

The aim of the LighTen Cohort study is to describe baseline clinical characteristics and long-term outcomes of patients using Tenofovir based antiretroviral therapy at the Lighthouse Clinics and to achieve the following objectives:

Objective 1:

*To determine the prevalence of renal dysfunction at enrolment and during follow-up among adult HIV-infected individuals starting ART.*

Objective 2:

*To determine the prevalence of HBV and HCV infections among adult HIV-infected individuals starting ART and during treatment follow-up.*

Objective 3:

*To determine the prevalence of non-communicable co-morbidities during treatment follow-up of HIV-infected individuals starting ART and during treatment follow-up.*

As primary outcome the study will determine:

Proportion of HIV-infected individuals with renal dysfunction using the CKD Epi formula at enrolment, 6 months, 12 months, 24months and 36 months post ART initiation



Secondary Outcomes will include the following proportions:

1. Proportion of HIV-infected individuals with HIV/ HBV and HCV infections 6 months, 12 months , 24 months and 36 months post ART initiation
2. Identifiable causes of renal dysfunction using urine-, serum analysis, urine Albumin /Creatinine ratio
3. Proportion of hypertension, diabetes at 6 months, 12 months, 24 months and 36 months post ART initiation
4. Proportion of viral resistance in a sub-cohort at ART initiation
5. Proportion of anaemia at enrolment
6. Proportion of tuberculosis at enrolment

### **Endorsement and enrolment**

The study protocol has been endorsed by the National Health Science and Research Committee, the Ethical Review Boards of the University Clinics Heidelberg and Cologne.

Enrolment started in July 2014 with the target is to enroll 1500 patients 18 years and older newly initiated on first line therapy. Follow up will be up for at least 36 months.

### **Contact**

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