Pharmacy and Poisons Board
Online clinical trials
Submitted Application : (ECCT/17/08/01)

Protocol No:	**ECCT/17/08/01**	Date of Protocol:	**20-04-2017**

Abstract of Study:

In July 2016, the demand for yellow fever vaccines in response to the large urban outbreaks occurring concurrently and the risk of further spread through the African continent and even to Asia, was larger than the available global supply. In this situation, the World Health Organization (WHO) developed recommendations for the use of fractional-dose of yellow fever vaccine as a dose-sparing strategy. These recommendations were based on data from a limited number of clinical trials and additional studies should be conducted assess the applicability of the fractional dose to all WHO-prequalified vaccines, the persistence of neutralizing antibodies and the performance of the fractional dose in young children and populations in Africa including those with HIV. This study aims to respond to some of the research questions that would allow broadening the recommendations on the use of fractional doses of yellow fever vaccine in emergency situations. The study will be conducted in Uganda (Mbarara, MSF Epicentre) and in Kenya (in KEMRI CGMR-C). The main objective is to assess the non-inferiority of seroconversion 28 days after vaccination of a fractional dose compared to full dose for each WHO-prequalified manufacturer. As secondary objectives the study will assess seroprotection 10 days and 1 year after vaccination, to assess rapidity and persistence of protective antibody levels; describe the geometric mean titre and the change in neutralizing antibody 28 days after vaccination with fractional and full doses; and assess the occurrence of adverse events and serious adverse events (SAE) during 28 days after administration of fractional and full doses. The study consists of a randomized non-inferiority trial. The study aims to start in April 2017 in the two sites and aims to recruit 960 adults (i.e. 480 per site) for the main study. Results for the safety and primary outcome for the main study will be reviewed by the study Data and Safety Monitoring Board and one vaccine will then be selected for the studies in children (n=418) and HIV positive adults (n=250). Both sites will participate in the main study (i.e. 480 adults per site), whereas the sub-study in children will be done in Mbarara and the sub-study in HIV positive adults will be conducted in Kilifi.

Study Title:

A Phase IV randomized, double blinded non-inferiority trial on the immunogenicity and safety of fractional doses of yellow fever vaccines.