



Short facts

Project Title: Safety and efficacy of dolutegravir and EFV400 for pregnant and breastfeeding women: a randomised non-inferiority clinical trial

Acronym: PREGART

Collaborative Project: Horizon 2020, the European Union's Framework Program for Research and Innovation.

Grant agreement: RIA2017MC-2009

Project Coordinator: Dr Birkneh Tadesse, MD, PhD– Hawassa University, Ethiopia

Project start date: 01 June 2019

Duration: 5 years (60 months)

Funding Organization: EDCTP

EDCTP grant amount: EUR 3,902,469

EDCTP Call: Clinical trials to reduce health inequities in pregnant women, newborns and children – 2017

Main objective: the project aims to provide evidence-based recommendations for safe and effective first line ART regimens for prevention of mother to child transmission and treatment of HIV infected pregnant and breastfeeding women living in resource limited settings. The study will contribute towards optimization of existing WHO and regional guidelines of ART for HIV infected pregnant and breastfeeding women.

Trial design: Multicenter, interventional, double blind, parallel assignment, and controlled three-arm non-inferiority randomized clinical trial.

Partner organizations

Hawassa University (HU), Ethiopia - Dr Birkneh Tadesse, MD, PhD

Makerere University (MU), Uganda – Dr Jackson Mukonzo, PhD

Karolinska Institutet (KI), Sweden – Associate Professor Eleni Aklillu, PhD

Istituto Superiore di Sanità (ISS), Italy - Marco Simonelli, PhD & Prof Stefano Vella, MD, PhD