POOR OUTCOME IN EARLY-TREATED HIV-PERINATALLY INFECTED INFANTS IN AFRICA

00806

Alfredo Tagarro[1,9], Sara Domínguez-Rodríguez[1], Avy Violari[2], Mark Cotton[3], Tacilta Mhampossa[4], Nigel Klein[5], Nastassja Ramsagar[2], Anita Janse Van Rensburg[3], Osse Behuhuma[5], Paula Vaz[6], Andrea Oletto[7], Paolo Palma[8], Paolo Rossi[8], Pablo Rojo[1], on behalf of the EPIICAL Consortium

1 Pediatric Infectious Diseases Unit, Fundación para la Investigación Biomédica del Hospital 12 de Octubre. 2 Perinatal HIV Research Unit, Chris Hani Baragwaneth Hospital, University of the Witwatersrand. Johannesburg, South Africa. 3 Tygerberg Children's Hospital, Stellenbosch University, Cape Town, South Africa. 4 Centro de Investigaçao em Saude de Manhiça (CISM) and Barcelona Institute for Global Health. Barcelona, Spain. 5 Africa Health Research Institute. Durban, South Africa 6 Fundaçao Ariel Glaser contra o SIDA Pediatrico. Maputo, Mozambique. 7 PENTA Foundation. Padova, Italy. 8 Research Unit in Congenital and Perinatal Infections, Academic Department of Pediatrics (DPUO), Division of Immunology and Infectious Diseases, Bambino Gesù Children's Hospital. Rome, Italy. 9 Hospital Universitario Infanta Sofía. Universidad Europea de Madrid. Madrid, Spain.

BACKGROUND

- HIV-infected infants should be treated early after diagnosis.
- Mortality and morbidity peak in the first 6 months after ART initiation and in infants < 1-year-old.
- Mortality is linked to advanced disease at diagnosis. There are few data about **determinants of poor outcome in early-treated infants.**

AIM

To assess **risk factors for poor outcome** despite **early ART** in a cohort of infants in South Africa and Mozambique

METHODS

EARTH is a multi-centre cohort enrolling HIV-infected infants diagnosed and **treated in the first 3 months of life.**

Enrolment started in May 2018. ART regimens followed national guidelines.

Poor outcome was defined as mortality or severe disease (progression to WHO clinical stage 3 or 4 or CD4 below 25%).

Risk factors for poor outcome and viral load (VL) suppression adjusting for socio-demographics, clinical, immunological and virological measures were assessed by multivariable time-dependent Cox-proportional hazards model, including time-dependent coefficient for follow-up VL and CD4.

RESULTS

To date, 135 infants were enrolled.

- 12 (9%) of infants died, 7 (5%) progressed to stage 3 or 4, and 16 (12%) had CD4 <25%.
- **32 (24%) had poor outcomes.**
- **34 (25%) infants suppressed VL** during follow-up at a median time **of 5.2 months.**
- **Determinants of poor outcome were VL during follow-up** (not baseline) and **age at ART**, after adjustment by site, baseline WAZ and ART regimen. (Figure 1)

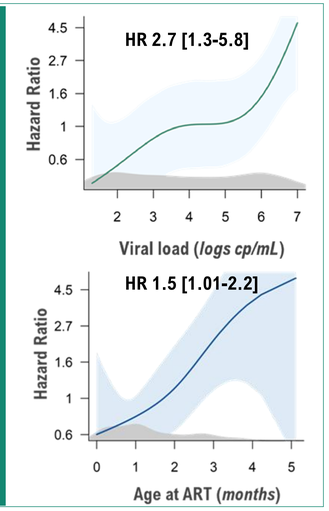
THE RISK OF POOR OUTCOME IN EARLY TREATED INFANTS WAS

- 3 TIMES HIGHER PER EACH LOG10 (VL) DURING FOLLOW-UP
- 1.5 TIMES HIGHER PER MONTH THAT ART WAS DELAYED

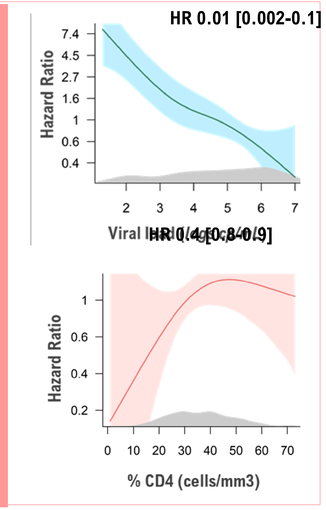
THE TIME TO SUPPRESSION WAS INFLUENCED BY

- BASELINE VL
- MATERNAL SEVERE LIFE EVENTS OR HEALTH ISSUES

TIME TO DEATH/ PROGRESSION/ <25%CD4



TIME TO SUPPRESSION



- 135 infants
- Follow-up time 5.5m [2.7-6.9]
- Age at enrolment 38d [31-75]
- Age at ART 38d [31-75]
- 46% females
- 30% WAZ ≤ -2SD
- 80% ART prophylaxis
- 79% 3TC+AZT/ABC+LPV/r
- 84% Breastfeeding at enrollment
- 100% Mothers alive
- 41% Mothers with severe life-events/ health-issues

CONCLUSIONS

Despite early ART, a significant proportion of infants had a poor outcome during the first months of life. The poor outcome is mainly influenced by viral load during follow-up and time to ART