This project (RIA2019PD-2887) is part of the EDCTP2 programme supported by the European Union

PedMAb: on your marks, get set, go!

Phase I/II study to determine Safety and Pharmacokinetics of subcutaneous administration of potent and broad anti HIV-1 neutralizing monoclonal antibodies (bNab), given to HIV-1 exposed neonates and infants.

EDCTP2 grant RIA2019PD – 2887. Funding period: 1 May 2021 – 31 October 2024.

Breastmilk optimizes child survival in low-middle income high HIV prevalence settings. However, breastmilk transmission of HIV continues to contribute to residual HIV mother-to-child transmission. PedMAb's aim is to ensure the development of a promising HIV-MTCT prevention strategy with broad anti-HIV-1 neutralizing monoclonal antibodies (bNAbs). The main objective is to complete two clinical trials, to define the optimal dose(s), timing, and the ideal combination(s) of bNAbs administered to breastfeeding HIV exposed uninfected neonates and infants born to HIV-infected women. https://pedmab.w.uib.no/about/ and https://pedmab.samrc.ac.za/.

The long acting (LS) version of the bNAbs CAP256, never tested in pediatric populations, and VRC07-523, were chosen for their characteristics. They target different viral regions involved in cell entry - the V1/V2 glycan region and CD4-binding (CAP256V2.LS) site of the HIV envelope; they have neutralization breadth for HIV subtype C (dominant in South Africa) and other subtypes to cover also viruses circulating in other high prevalent areas beside South Africa; and their potency and availability of the formulation for subcutaneous administration, which in children is preferable to intravenous administration.

The PedMAb consortium held their second annual meeting in Durban, South Africa 13-14 April 2023. Day 1 was at the South African Medical Research Council and Day 2 was at the MRC Chatsworth clinical research site located at the R.K. Kahn Hospital. The meeting brought together the entire PedMAb Consortium, from Milan, Italy; Montpellier, France; Bergen Norway and South Africa. Partners reviewed trial progress and further developed technical approaches. Thus far arm 1 with the low dose of CAP256V2LS (5 mg/kg) is fully enrolled with eight neonates. All who have completed the 6 months follow-up visits with 100% retention. Currently randomized recruitment is almost complete for Arms 2 (CAP256V2LS at 10 mg/kg) and 4 (VRC07-523LS at 20 mg/ml). Safety data has been reviewed two-weekly and all adverse events have not been related to the study product. PK data are currently being analysed.

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The PedMAb Team at the South African MRC clinical research site at Chatsworth, Durban, South Africa.