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POSTER ABSTRACTS

114.SICKLE CELL DISEASE, SICKLE CELL TRAIT, AND OTHER HEMOGLOBINOPATHIES, EXCLUDING THALASSEMIAS: CLINICAL AND EPIDEMIOLOGICAL

Learner- Low Dose Aspirin Preterm Trial (Angola). Low Dose Aspirin in Pregnant Women with Sickle Cell Disease When Started in the First Versus Second Trimester- a Clinical Control Study in Angola

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Sickle Cell Disease (SCD) is marked by episodes of acute vaso-occlusive crises, severe anemia, acute chest syndrome, multi-organ damage and stroke, among others. Pregnancy in these patients is associated with an increased risk of adverse outcomes, such as intrauterine growth restriction, perinatal and maternal mortality, low birth weight, eclampsia, pre-eclampsia, and stroke. Therefore, increasing the surveillance during pregnancy and searching prophylactic solutions for early prevention of pregnancy complications in women with SCD in African countries, where the burden of SCD is disproportionally higher, is an urgent need.

Aspirin is already widely prescribed for the prevention of cardiovascular complications, and at a low daily dose, is used during pregnancy to prevent preeclampsia, intrauterine growth restriction, and other maternal-and-fetal disorders. In pregnant women with SCD, low dose aspirin is considered safe and is recommended for those who are at severe risk of pre-eclampsia. LEARNER (ClinicalTrials.gov ID, NCT06417411), is a prospective, opened label study to evaluate the effects of daily low dose aspirin in pregnant women with SCD when initiated at the first trimester versus the second trimester of the gestational period (where it is frequently started). We hypothesize that a low dose of aspirin (100 mg/daily) initiated early in pregnancy (weeks 6-13) can be more beneficial, than when it is started in the second trimester (weeks 14-27), reducing the incidence of fetal and maternal complications. This study intends to quantify the reduction in preterm delivery, perinatal death/miscarriage, and the risk of other maternal complications including pre-eclampsia, hypertensive disorders, number of vaso-occlusive crises, need for blood transfusion, urinary tract infections, respiratory tract infections, acute chest syndrome, retained placenta, placental abruption, and vaginal bleeding, when initiating low dose aspirin in the earliest stage of the gestation period.

A total of 450 pregnant women, with confirmed diagnosis of SCD, will be enrolled in this study. Enrollment is taking place at maternity and infant hospitals in Luanda, Angola. Patients who consent to participate in the study will be assigned to one of two groups based on their gestational age, confirmed through ultrasound. Participants will then start daily use of 100 mg aspirin; dosing will be suspended at time of delivery, week 36, or earlier, if deemed necessary by the clinical team. Participants will be followed from the consenting visit to 6 weeks post-partum.

Recruitment started in April 2024, after regulatory approval (local EC approval nº52/CEMS/2023, and national IRB approval 99/ARMED/MINSA/2024), and to date, 15 participants have been consented and 10 are in the treatment period. The biggest challenge to date is recruiting participants in the first trimester as most pregnant women that visit the hospital, in Angola, are already at the end of the second or in the third trimester. Our strategy to increase the study's visibility and facilitate patient recruitment will be advertisements in social media and patient support groups and to reach out to local health centers around Luanda.

Additionally, this study aims to build capacity in Angola for the conduction of future clinical trials, involving local research sites and hospitals, capacitating Angolan institutions and professionals in clinical trial conduction and data capture abilities, promoting national and international collaborations, and creating population awareness for clinical research studies. The study team is comprised of the scientific team, local clinical team, an electronic data capture specialty team, a site management

organization (SMO), and a Contract Research Organization (CRO). This is the first of its kind in Angola, which will revolutionize research in the country and help with our understanding of many diseases by diversifying the studied population pool for SCD and all other research that will be conducted in the country following the model established by this study.
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Disclosures No relevant conflicts of interest to declare.

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