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Abstract Title : Implementation challenges of the learner clinical trial in pregnant women with sickle cell disease in Angola

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Abstract Body

Sickle Cell Disease (SCD), a severe inherited blood disorder, poses significant risks during pregnancy, particularly in regions like Sub-Saharan Africa, where its prevalence is high. Pregnancy often intensifies the complications associated with SCD, including severe anemia and vaso-occlusive crises, while also elevating the risk of obstetric complications such as pre-eclampsia, eclampsia, intrauterine growth restriction, low birth weight, and maternal or fetal death. These heightened risks underscore the critical importance of close medical surveillance throughout pregnancy. Moreover, there is an urgent need to identify affordable, preventive strategies, especially in low- and middle-income countries where health systems are often overburdened and resources limited. Considering these critical needs, clinical research initiatives like the LEARNER clinical study (NCT06417411) are extremely important to develop and evaluate interventions that could improve outcomes for pregnant women with SCD in Sub-Saharan Africa. However, conducting such research in countries like Angola is fraught with complex implementation challenges. These include resource limitations in both the research sites and the patient population, and societal norms related to prenatal visits,

The use of daily low-dose aspirin is considered safe in pregnant women with SCD and is recommended after 12 weeks of gestational age by the British Society of Hematology for those at severe risk of pre-eclampsia. The LEARNER Study aims to evaluate the effects of daily low-dose aspirin in SCD pregnancy, comparing its impact on severe outcomes if this prophylactic and affordable medication is started in the first or the second trimester.

This study aims to recruit 450 pregnant women with a confirmed SCD diagnosis in multiple maternity and infant hospitals in Luanda, Angola. Consenting patients will be assigned to the first (weeks 6-13) or second (weeks 14-27) trimester groups according to their gestational age, as confirmed by ultrasound. Participants will start daily low-dose aspirin and will do regular follow-up appointments till 6 weeks postpartum. Aspirin will be interrupted at week 36, delivery time, or earlier if decided by the clinical team.

Although challenges in patient recruitment and clinical research conduct were anticipated, the LEARNER study revealed several specific barriers within the Angolan context, particularly the pregnant women patient population. Efforts to recruit participants included television and radio interviews, social media campaigns, WhatsApp group messages, and outreach visits to other hospitals in the Angola capital city, Luanda. Despite these strategies, recruitment was hampered by persistently low adherence to early prenatal visits and limited awareness of clinical research. However, overall community and local support for clinical trials has been positive, making the outlook for future research projects in Angola very promising.

Recruitment started in March 2024, after ethical and regulatory approvals (Parecer n°52/CEMS/2023, and 99/ARMED/MINSA/2024). In 16 months, 120 women were enrolled in the study, 60 in the first trimester and 60 in the second trimester. To date, 271 severe events, 3 associated with the medication, 9 cases of pre-eclampsia/eclampsia, 36 preterm deliveries, 5 miscarriages, 1 perinatal death, and 4 maternal deaths were registered.

The current sample size is too small to draw statistically significant conclusions about the efficacy of starting low-dose daily aspirin earlier in pregnancy. The number of enrolled patients is below the expected, as most pregnant women tend to seek hospital care only during the later stages of pregnancy. To ensure interventions like the LEARNER study are successfully conducted, it is urgent to invest in health literacy and SCD education in Angola and increase patients' awareness of the need to do prenatal and follow-up consultations during pregnancy for the prevention of pregnancy-associated complications in women.

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