RESEARCH TO EXPAND ACCESS TO Heat-Stable Carbetocin for the Treatment of Postpartum Haemorrhage (REACH)

Current Project Brief

This project will focus on generating primary research evidence on the safety and efficacy of heat-stable carbetocin (HSC) for postpartum haemorrhage treatment, to build an evidence ecosystem that will enable the right conditions for scale-up of HSC at global and country levels.

Objectives and Background

Postpartum haemorrhage (PPH) is the leading cause of maternal death globally, accounting for about 70,000 maternal deaths annually. Women who survive PPH often suffer acute or longer-term disabilities that may impact on their future health and well-being and reproductive functions. The majority of maternal deaths associated with PPH occur in low- and middle-income countries (L/MICs), and are largely preventable with appropriate interventions.
HSC, a heat-stable analogue of oxytocin (the standard treatment for the control of PPH) can help to change the trajectory of PPH-related mortality. However, there are significant policy, programme, and supply chain barriers that impede HSC use in settings where it could save lives. To address these gaps in the global response to the public health and market shortcomings related to HSC, we propose as the main focus of a broader project to expand access to HSC, a phase III, randomized, double-blind, active controlled, multicountry, multicentre, non-inferiority trial to evaluate whether HSC is non-inferior to oxytocin for treatment of PPH in women who receive HSC for PPH prophylaxis, in the prevention of additional blood loss of 500 ml or more. The trial will include 6,200 women delivering vaginally and diagnosed with PPH. Participants' recruitment is aimed to start in Q3 -2023 and finalize in Q4 – 2026.

Geographic location

Argentina, India, Kenya, Nigeria, South Africa, Uganda, and the United Kingdom.

Main deliverables

The new knowledge generated on the safety and efficacy of HSC for PPH treatment will be widely disseminated and integrated into existing body of evidence, to update WHO recommendations on the use of HSC for PPH management. At country level, evidence and policy briefs will be developed for programme managers and policy makers to enhance the national capacity in using the new evidence. Should the clinical trial demonstrate that HSC is safe and non-inferior to oxytocin for PPH treatment, it is expected that global and national PPH treatment guidelines will be updated, the indication for HSC would be extended to include PPH treatment in the WHO Essential Medicines List, and regulatory agencies would extend the indication of HSC to PPH treatment. These

outcomes aim to eliminate the current barrier to scaling up HSC as a dependable uterotonic option in settings where oxytocin quality cannot be guaranteed.

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