Refractory haEmorrhage Devices trial: a multi-arm, multi-stage, multicentre randomized active controlled superiority trial to evaluate the efficacy of uterine tamponade devices for the management of refractory postpartum haemorrhage. (RED trial)

Current Project Brief

The objective of this trial is to compare the efficacy of three uterine tamponade devices (Ellavi® free-flow, Ellavi® fixed-volume, or STUT) with that of the site specific improvised UBT (Foley catheter), in reducing the incidence of severe maternal morbidity or mortality in women who delivered vaginally and were diagnosed with atonic refractory PPH.

Objectives and Background

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality in low-income countries and it contributes to nearly a quarter of maternal deaths globally. Postpartum haemorrhage caused by uterine atony may not respond to first-line treatment with uterotonic drugs; and is defined as refractory PPH. In such cases, uterine tamponade is a promising non-surgical alternative, before undertaking any invasive surgical procedures. Although balloon tamponade devices have been widely used, there is no consensus about the most effective and safe one. Therefore, we are conducting an adaptive, hospital-based, multicentre, multi-arm, multi-stage (MAMS), individually randomized active-controlled superiority trial to evaluate the efficacy of different uterine tamponade devices for the treatment of refractory PPH in women delivering vaginally.
The trial started in July 2022 and is currently ongoing. It is planned to include 680 women in its first stage.

Geographic location

Vietnam

Main deliverables

The RED trial is aiming to evaluate critical non-surgical interventions for the management of refractory PPH and thus improve the quality of available evidence regarding the efficacy and safety of different uterine tamponade devices. There is no reliable evidence for any of the interventions under evaluation. The generated evidence will enable WHO to adequately update the current recommendations on the role of uterine tamponade devices in the management of atonic refractory PPH cases. Apart from WHO, local stakeholders and policy makers may also use trial findings to promote changes in clinical practise, aiming to improve emergency obstetric care provided on local or national level.

Sources of funding

HRP