WHO Champion Trial Investigators Meeting

The World Health Organisation (WHO) held a Champion Trial Investigators Meeting between 7th and 8th March 2016 in Belgaum, India. This was a Phase III, Randomized, Double-Blind, Active Controlled, Multinational, Multicentre, Non-Inferiority Trial Using Carbetocin Room Temperature Stable (Rts) for the Prevention of Postpartum Haemorrhage during the Third Stage of Labour in Women Delivering Vaginally.

Postpartum haemorrhage (PPH) is defined as a blood loss of 500 mL or more within 24 hours of delivery, while severe PPH (sPPH) is defined as a blood loss of 1000 mL or more within the same time frame. PPH is the leading cause of maternal mortality in low-income countries and it contributes to nearly a quarter of maternal deaths globally. PPH is a significant contributor to severe maternal morbidity and long term disability, as well as to a number of other severe maternal conditions, generally associated with more substantial blood loss, including shock and organ dysfunction. The majority of deaths due to PPH could be avoided through the use of prophylactic uterotonics during the third stage of labour and by timely and appropriate management. Oxytocin (Intramuscular/intravenous [IM/IV] 10 IU) is recommended as the uterotonic drug of choice.

The Champion trial had two primary objectives:

(1) To evaluate non-inferiority of carbetocin RTS 100 µg IM versus oxytocin 10 IU IM after vaginal delivery in the prevention of the composite endpoint “blood loss of 500 mL or more or the use of additional uterotonics” at one hour and up to two hours for women who continue to bleed after one hour.

(2) To evaluate non-inferiority of carbetocin RTS 100 µg IM versus oxytocin 10 IU IM in the prevention of sPPH (≥1000 mL blood loss) at one hour and up to two hours for women who continue to bleed after one hour.