Oral Misoprostol – A Placebo controlled trial

Bleeding after childbirth (postpartum haemorrhage or PPH) accounts for nearly one quarter of all maternal deaths worldwide.

The current WHO recommendation to prevent PPH is *'active management of third stage labour'*. This involves three procedures: an immediate post-delivery oxytocin injection, delivery of the placenta by cord traction, and a uterine massage.

When conducted by skilled birth attendants, these activities together reduce PPH by over 60%.

In many countries, however, women deliver at home accompanied by birth attendants who are neither trained nor certified to administer injections including oxytocin.

Therefore, we are proposing testing misoprostol administered orally in tablet form as an alternative to an oxytocin injection.

We believe misoprostol may prove to be a good alternative for women in countries where resources, including skilled medical practitioners, are scarce.

Our hypothesis is that misoprostol administered orally during the third stage of labour will reduce the rate of acute PPH by 50% compared to women given a placebo.

Our 3-year study will be conducted in 4 primary health centres in one state in India. In these villages, more than half the deliveries are home-births or at sub-centres where no doctors are available.

We think that using a placebo is justified in this setting. Even though ocytocin by injection is the standard of care in India for women delivering in *district hospitals*, it is *not* available at the primary health care level.

There are *no signs that this will change in the near future.*

Oxytocin is not, therefore the *real* local standard of care.

Instead, auxiliary nurse midwives practice "expectant management", that is, no uterotonics at all are used, leaving the women highly vulnerable.

Misoprostol has some advantages:

It can be administered in non-hospital settings by birth attendants with minimal training and it's relatively inexpensive. It also has a long shelf life and it does not require refrigeration.

In this trial. a single oral dose of misoprostol or placebo will be administered by the midwife after delivery of the baby and within 5 min of clamping and cutting of the umbilical cord.

The midwives participating will be trained and be responsible for screening out and referring high risk women to other facilities. They will recruit study participats during the antepartum period and will obtain informed consent at that time.

Thank you for considering this important study.