



# Simplified Treatment for Eclampsia Prevention using Magnesium Sulfate

## **Current Project Brief**

### Objectives and Background

Pre-eclampsia and eclampsia are significant contributors to maternal morbidity and mortality globally accounting for more than 40,000 maternal deaths annually. Magnesium sulphate (MgSO<sub>4</sub>) is currently the anticonvulsant of choice for the prevention and control of eclamptic fits. Although two recommended regimens have been internationally accepted as standard regimens on the basis of their proven clinical efficacy in the largest MgSO<sub>4</sub> trials, these trials also revealed the lack of understanding of the minimum effective dose for eclampsia prevention and treatment. More recently, concerns about adverse events from the use of standard regimens and coverage limitations posed by health resource requirements have renewed interests in identifying the minimum effective dose of MgSO<sub>4</sub> for treating pre-eclampsia and eclampsia.

In collaboration with Merck for Mothers, the Department of Reproductive Health and Research, World Health Organization is planning an international, multicenter, randomized non-inferiority trial to test a simpler magnesium sulphate (MgSO $_4$ ) regimen for preventing and treating eclampsia in pregnant mothers. A number of converging research activities have been identified to inform the implementation of a non-inferiority trial that will compare the simpler MgSO $_4$  regimen with currently recommended standard regimens.

#### Geographic location M

Multi-country

#### Main deliverables

- (1) Systematic review of clinical pharmacokinetic properties of magnesium sulphate in women with pre-eclampsia and eclampsia
- (2) Update of the existing Cochrane review on alternative regimens of magnesium sulphate for the prevention and treatment of eclampsia
- (3) Systematic review of observational studies comparing alternative regimens of magnesium sulphate for prevention and treatment of eclampsia
- (4) Multi-country survey of clinical practice pattern on the use of magnesium sulphate for preeclampsia and eclampsia
- (5) Magnesium sulphate pharmacokinetic and pharmacokinetic (PK/PD) modelling and simulation
- (6) Planned multi-country randomized controlled trial to evaluate the efficacy and safety of a simplified magnesium sulphate regimen for the prevention and treatment of eclampsia upon findings of PK/PD study

**Partners** 

WHO Multi-country Survey Network; University of Oxford, UK; University of Stanford, USA; Khon Kaen University, Thailand; Merck for Mothers, USA; Nottingham Clinical Trials Unit, UK

Sources of funding

Merck for Mothers

**Date Issued** 

December 2015