



Patient information leaflet

This information leaflet is for women attending antenatal care in participating facilities in **[COUNTRY]**, and who may like information on a trial we are conducting on use of magnesium sulfate for women with pre-eclampsia. If you develop pre-eclampsia during your pregnancy, childbirth or 24 hours after giving birth you may decide to participate in the study.

The title of our research project is " A66014: **Simplified Treatment for Eclampsia Prevention** using **Magnesium** sulfate: An open label, active controlled, multinational, multicenter, randomized non-inferiority trial of simplified magnesium sulfate regimen for eclampsia prophylaxis (The STEPMag Trial)"

[Name of Principal Investigator]
[Name of Organization]
SPONSOR: World Health Organization
[Name of Proposal and version]

Purpose of the research

Pre-eclampsia and eclampsia are conditions that can develop in pregnant women. Pre-eclampsia affects around 5% of all pregnancies. Women with pre-eclampsia will have high blood pressure in addition to other symptoms like headache, abdominal (belly) pain, nausea or vomiting late in pregnancy, or severe swelling such as in the woman's hands or face. If serious the women may also have a seizure or convulsion known as eclampsia. Both pre-eclampsia and eclampsia can cause a woman to be very sick and, in some cases even die.

When women have pre-eclampsia, a medicine called magnesium sulfate is used to prevent the woman having serious complications including seizures/convulsions (eclampsia). Normally the magnesium sulfate is given through multiple muscle injections (an injection with a needle into the buttocks) or an intravenous infusion (a small needle with a tube is inserted into a vein on the hand). Sometimes both an injection into the buttocks and a small needle/tube into the hand are used. The small needle and tube in the hand brings the medication into the veins. No matter which way it is given, your health care provider needs to monitor for signs of too much magnesium (magnesium toxicity).

Magnesium sulfate is widely accepted as a life-saving drug and used in many countries including NAME OF COUNTRY. However, as giving magnesium can require giving many injections and the woman needs to be monitored for too much magnesium (magnesium toxicity), in some settings the woman can only receive treatment in high-level facilities, such as a hospital. Although magnesium sulfate is a life-saving drug it can cause some pain and irritation at the injection site in the buttocks for muscle injections or in the hand for the intravenous line.

We are trialing a simpler regimen of giving magnesium sulfate which may involve giving fewer injections. We need to see if the simpler regimen also prevents seizures/convulsions and complications in the same way that using the standard treatment does and is safe for mothers and their babies. It is hoped that this will allow more women in low-level facilities to get magnesium sulfate (as it will be less complicated) and that women will experience less discomfort. If we find that the simple treatment is as good (or even better), then it will likely mean that more women, in more places, who need magnesium because of pre-eclampsia/eclampsia will be able to receive this life-saving medicine.

Type of Research Intervention

This research would involve some injections into the buttocks and/or intravenously (through an intravenous line in the hand). Up to 7 injections may be given (this is the standard treatment that your hospital would normally give you).

Participant selection

You will be invited to participate if you have pre-eclampsia and if you attend this hospital for birth to participate in this research.

Voluntary Participation

Your participation in this research would be entirely voluntary. It is your choice whether to participate in the future or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change.

If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital. You may change your mind and stop participating, even if you agreed earlier.

Costs to participate in the study

There will be no additional costs incurred by you or your family if you chose to participate in the study.

Contact

If you have pre-eclampsia or develop pre-eclampsia you can contact us to participate.