

For more information about the trial
please contact:

Magpie Trial Co-ordinating Centre
Institute of Health Sciences
Old Road
Headington
Oxford
OX3 7LF
United Kingdom

Tel: +44 (0) 1865 226642
Fax: +44 (0) 1865 227173
Email: magpie@ndm.ox.ac.uk



MAGPIE TRIAL

Magnesium sulphate for
treatment of pre-eclampsia:
*A trial to evaluate the effects on
women and their babies*

SUMMARY PROTOCOL

The Magpie Trial is funded by the Medical Research Council, Department for International Development, World Health Organisation and the European Commission

The Magpie Trial aims to assess whether using magnesium sulphate for treatment of women with pre-eclampsia leads to a substantive improvement in outcome for the women and/or their children.

Who can be entered into the Magpie Trial?

The **minimum** criteria for blood pressure and proteinuria are given below, but most women for whom magnesium sulphate is being considered will have higher levels. About a quarter of women who develop eclampsia have only moderate rises in blood pressure, and these criteria are to ensure that such women are not excluded.

Women ARE eligible for trial entry if:

- Clinician is 'uncertain' of the benefits and risks of magnesium sulphate for this woman * *and*
- Not delivered, or delivered within the last 24 hours *and*
- Blood pressure $\geq 90\text{mmHg}$ diastolic or $\geq 140\text{mmHg}$ systolic *and*
- Proteinuria of $\geq 1+$ *and*
- Consent has been given

* uncertainty is likely to be influenced by signs or symptoms of imminent eclampsia.

Women are NOT eligible for trial entry if:

- Clinician is 'certain' of the benefits and risks of magnesium sulphate for this woman
- Hypersensitivity to magnesium sulphate
- Hepatic coma with risk of renal failure
- Myasthenia gravis
- Consent has been not given

Interventions being compared

Magnesium sulphate is being compared to placebo. Both are given as a loading dose followed by 24 hours maintenance therapy. Each hospital decides whether to use the IM or IV regimen for maintenance therapy. The trial drug is supplied in numbered sealed treatment packs. All trial materials are supplied by the Magpie Trial Co-ordinating Centre.

Main outcomes and size of the trial

The primary measures of outcome are eclampsia and, for women randomised before delivery, death of the baby. Other outcomes to be assessed include measures of serious maternal and neonatal morbidity, complications of labour and delivery, use of health service resources, toxicity and side effects. The estimated sample size is 14,000 women.

Follow-up of women and babies

Follow-up information is based on clinical data only. No additional investigations are required. Whenever possible, information about outcome is collected at the time of discharge after delivery.

Entering women into the trial

Trial entry of eligible women who have given consent is by means of a telephone call to a 24-hour randomisation service in Oxford, freephone in the UK. Hospitals without reliable telephone access will use a local pack system. Once the treatment pack has been allocated the treatment is given and the women monitored by checking tendon reflexes, respiratory rate and urine output.