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A randomised controlled trial of intravenous magnesium sulphate versus placebo in the management of women with severe pre-eclampsia

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Objective To determine whether the administration of prophylactic intravenous magnesium sulphate reduces the occurrence of eclampsia in women with severe pre-eclampsia.

Design Randomised controlled trial.

Setting A tertiary referral obstetric unit.

Population Eight hundred and twenty-two women with severe pre-eclampsia requiring termination of pregnancy by induction of labour or caesarean section.

Methods The women were randomised to receive either placebo (saline) or magnesium sulphate intravenously. The investigators were blinded to the contents of the pre-mixed solutions.

Main outcome measure The occurrence of eclampsia in the two groups.

Results The data of 699 women were evaluated. Fourteen were withdrawn after randomisation. The overall incidence of eclampsia was 1·8% . Of 345 women who received magnesium sulphate, one developed eclampsia (0·3%); in the placebo group, 11/340 women (3·2%) developed eclampsia (relative risk 0·09; 95% confidence interval 0·01–0·69; $P = 0·003$).

Conclusion The use of intravenous magnesium sulphate in the management of women with severe pre-eclampsia significantly reduced the development of eclampsia.

INTRODUCTION

In 1990 when this study was planned there was still doubt as to the efficacy of magnesium sulphate in the management of eclampsia. Evidence was based on large descriptive studies such as those of Pritchard[1] and the small controlled studies comparing magnesium sulphate to phenytoin[2] or diazepam[3]. The Collaborative Eclampsia Trial[4] had not yet begun. There were no published studies comparing magnesium sulphate with placebo or to other therapies in the management of severe pre-eclampsia. There were differences of opinion regarding the use of prophylactic magnesium sulphate, or other anti-convulsants, in the management of women with severe pre-eclampsia. Sibai[5] advocated the use of magnesium sulphate, even in cases of moderate pre-eclampsia, while Redman[6] maintained that anti-convulsants were only indicated if eclampsia occurred. Therefore, a prospective randomised trial to determine whether with severe pre-eclampsia was commenced in October 1991, after approval by our Ethical committee.

METHODS

Women with severe pre-eclampsia admitted to the Groote Schuur Hospital Maternity Centre Tertiary Care Unit from secondary level hospitals, outlying clinics (midwife obstetric units) and from the antenatal wards of Groote Schuur Hospital were included in the trial. Only women with severe pre-eclampsia were included where a decision to terminate pregnancy had been made. Severe pre-eclampsia was defined as two or more of the following features: a diastolic blood pressure ≥ 110 mmHg, significant proteinuria, and symptoms of imminent eclampsia. Informed consent was obtained. Women younger than 16 years of age were excluded as there were difficulties in obtaining informed consent.