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# The 3Mg Trial: A Randomised Controlled Trial of Intravenous or Nebulised Magnesium Sulphate Versus Placebo in Adults With Acute Severe Asthma

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## Abstract

**Background:** Magnesium sulphate, administered by the intravenous (i.v.) or inhaled (nebulised) route, has been proposed as a treatment for adults with acute severe asthma. Existing trials show mixed results and uncertain evidence of benefit.

**Objectives:** We aimed to determine whether i.v. or nebulised magnesium sulphate improves symptoms of breathlessness and reduces the need for hospital admission in adults with acute severe asthma.

**Design:** Multicentre, double-blind, placebo-controlled, three-arm, randomised trial.

**Setting:** The emergency departments of 34 acute hospitals in the UK.

**Participants:** We recruited 1109 adults (age >16 years) with acute severe asthma [peak expiratory flow rate (PEFR) <50% of best/predicted, respiratory rate >25 breaths per minute, heart rate >110 beats per minute or inability to complete sentences in one breath]. Patients with life-threatening features or a contraindication to either nebulised or intravenous magnesium sulphate were excluded.

**Interventions:** Participants were randomly allocated to i.v. magnesium sulphate (2 g over 20 minutes) or nebulised magnesium sulphate (3 × 500 mg over 1 hour) or standard therapy alone.

**Main outcome measures:** The primary outcome was the proportion of patients admitted to hospital (either after emergency department treatment or at any time over the subsequent 7 days) and breathlessness measured on a 100-mm visual analogue scale (VAS) over 2 hours after initiation of treatment.

**Results:** We randomised 406 patients to i.v. magnesium sulphate, 339 to nebulised magnesium sulphate and 364 to placebo. Hospital admission was recorded for 394, 332 and 358 patients, respectively, and VAS breathlessness for 357, 296 and 323 patients respectively. Mean age was 36.1 years and 763 out of 1084 (70%) patients were female. Intravenous magnesium sulphate was associated with an odds ratio (OR) of 0.73 [95% confidence interval (CI) 0.51 to 1.04; p=0.083] for hospital admission, an improvement in VAS breathlessness that was 2.6 mm (95% CI -1.6 to 6.8 mm; p=0.231) greater than that associated with placebo and an improvement in PEFR that was 2.4 l/minute (95% CI -8.8 to 13.6 l/minute; p=0.680) greater than that associated with placebo. Nebulised magnesium sulphate was associated with an OR of 0.96 (95% CI 0.65 to 1.40; p=0.819) for hospital admission, an improvement in VAS breathlessness that was 2.6 mm (95% CI -1.8 mm to 7.0 mm; p=0.253) less than that associated with placebo and an improvement in PEFR that was 2.6 l/minute (95% CI -9.2 to 14.5 l/minute; p=0.644) less than that associated with placebo. There were no significant differences between i.v. or nebulised magnesium sulphate and placebo for any other outcomes. The number (%) of patients reporting any side effect was 61 (15.5%) in the i.v. group, 52 (15.7%) in the nebuliser group and 36 (10.1%) in the placebo group. The ORs for suffering any side effect were 1.68 (95% CI 1.07 to 2.63; p=0.025) for i.v. compared with placebo and 1.67 (95% CI 1.05 to 2.66; p=0.031) for nebuliser compared with placebo.

**Conclusions:** We were unable to demonstrate a clinically worthwhile benefit from magnesium sulphate in acute severe asthma. There was some weak evidence of an effect of i.v. magnesium sulphate on hospital admission, but no evidence of an effect on VAS breathlessness or PEFR compared with placebo. We found no evidence that nebulised magnesium sulphate was more effective than placebo.

**Trial registration:** Current Controlled Trials ISRCTN04417063.

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