Randomized Controlled Trial

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**Efficacy of early neonatal supplementation with vitamin A to reduce mortality in infancy in Haryana, India (Neovita): a randomised, double-blind, placebo-controlled trial**

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**Abstract**

**Background:**Vitamin A supplementation in children aged 6 months to 5 years has been shown to reduce mortality. The efficacy of neonatal supplementation with vitamin A to reduce mortality in the first 6 months of life is plausible but not established. We aimed to assess the efficacy of neonatal oral supplementation with vitamin A to reduce mortality between supplementation and 6 months of age.

**Methods:**We undertook an individually randomised, double-blind, placebo-controlled trial in Haryana, India. We identified pregnant women through a surveillance programme undertaken every 3 months of all female residents in two districts of Haryana, India, aged 15-49 years, and screened every identified livebirth. Eligible participants were neonates whose parents consented to participate, were likely to stay in the study area until at least 6 months of age, and were able to feed orally at the time of enrolment. Participants were randomly assigned to receive oral capsules containing vitamin A (retinol palmitate 50,000 IU plus vitamin E 9·5-12·6 IU) or placebo (vitamin E 9·5-12·6 IU) within 72 h of birth. Randomisation was in blocks of 20 according to a randomisation list prepared by a statistician not otherwise involved with the trial. Investigators, participants' families, and the data analysis team were masked to treatment allocation. The primary outcome was mortality between supplementation and 6 months of age. Analysis included all participants assigned to study groups. This trial is registered with ClinicalTrials.gov, number [NCT01138449](http://clinicaltrials.gov/show/NCT01138449), and the Indian Council of Medical Research Clinical Trial Registry, number CTRI/2010/091/000220.

**Findings:**Between June 24, 2010, and July 1, 2012 we screened 47,777 neonates and randomly assigned 44,984 to receive vitamin A (22,493) or placebo (22,491). Between supplementation and 6 months of age, 656 infants died in the vitamin A group compared with 726 in the placebo group (29·2 per 1000 vs 32·3 per 1000; difference -3·1 per 1000, 95% CI -6·3 to 0·1; risk ratio 0·90, 95% CI 0·81 to 1·00). We noted no significant interactions between the intervention effect and sex on mortality at 6 months (p=0·409). Supplementation with 50,000 IU vitamin A within the first 72 h of life was generally safe and well tolerated, with the exception of a small excess risk of transient bulging fontanelle (205 cases in the vitamin A group confirmed by physician vs 80 cases in the placebo group, risk ratio 2·56 [95% CI 1·98-3·32]).

**Interpretation:**The findings of this study, done in a population in which vitamin A deficiency is a moderate public health problem, are consistent with a modest reduction in mortality between supplementation and 6 months of age. These findings must be viewed together with similar trials in other populations to enable determination of appropriate public health policy.

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