Naloxone for opiate-exposed newborn infants

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RHL summary

Findings of the review: This review sought to evaluate the benefits and risks of using naloxone to treat opiate-exposed newborn infants with cardio-respiratory or neurological depression. The primary outcomes of this review were admission to neonatal intensive or special care unit and failure to establish breast-feeding. Unfortunately, none of the nine included trials with 316 infants addressed these primary outcomes. Expired carbon dioxide output and alveolar ventilation rate were statistically significantly higher and carbon dioxide tension was statistically significantly lower in the naloxone group at 30 minutes and four hours post treatment. However, there was significant heterogeneity in the meta-analyses.

Implementation: Given the lack of evidence, naloxone use should be limited to randomized controlled trials evaluating the benefits and risks of naloxone in opiate-exposed newborn infants who have cardio-respiratory or neurological depression.

Cochrane review


Abstract

Naloxone, a specific opiate antagonist, is available for the treatment of newborn infants with cardiorespiratory or neurological depression that may be due to intrauterine exposure to opiate. It is unclear whether newborn infants may benefit from this therapy and whether naloxone has any harmful effects.

To determine the effect of naloxone as a treatment for newborn infants who have been exposed in utero to opiate.

We searched the following databases in June 2012 for new studies published since the previous search in 2007: The Cochrane Central Register of Controlled Trials (The Cochrane Library 2012, Issue 6), MEDLINE (OvidSP), MEDLINE In process & Other Non-Indexed Citations (OvidSP), EMBASE (OvidSP), CINAHL (EBSCO), Maternity and Infant Care (OvidSP) and PubMed. We searched for ongoing and completed trials in Clinical Trials.gov, metaRegister of Controlled Trials, WHO International Clinical Trials Registry Platform and the EU Clinical Trials Register. We checked the reference lists of relevant articles to identify
further potentially relevant studies.

Randomised controlled trials comparing the administration of naloxone versus placebo, or no drug, or another dose of naloxone to newborn infants with suspected or confirmed in utero exposure to opiate.

We extracted data using the standard methods of the Cochrane Neonatal Review Group with separate evaluation of trial quality and data extraction by two review authors and synthesis of data using risk ratio, risk difference and weighted mean difference.

We included nine trials that compared the effects of naloxone versus placebo or no drug in newborn infants exposed to maternal opiate analgesia prior to delivery. None of these trials specifically recruited infants with cardiorespiratory or neurological depression. The main outcomes reported were measures of respiratory function in the first six hours of life. There is some evidence that naloxone increases alveolar ventilation. The trials did not assess the effect on the primary outcomes of this review (admission to a neonatal unit and failure to establish breastfeeding).

The existing evidence from randomised controlled trials is insufficient to determine whether naloxone confers any important benefits to newborn infants with cardiorespiratory or neurological depression that may be due to intrauterine exposure to opiate. Given concerns about the safety of naloxone in this context it may be appropriate to limit its use to randomised controlled trials that aim resolve these uncertainties.

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