

# Are Neonatal Trials Better Conducted and Reported over the Last 6 Decades? An Analysis on Their Risk-of-Bias Status in Cochrane Reviews

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## What Is Already Known on This Topic

- There are well-established tools to assess the quality of a randomized controlled trial (RCT). However, there has not been any published report on the quality of a representative sample of neonatal RCTs since the first neonatal trial was conducted.

## What This Study Adds

- An assessment of the risk-of-bias profile of all RCTs in Cochrane neonatal reviews shows that while the overall quality of neonatal RCTs has improved over the last 6 decades, blinding remained unsatisfactory in the majority of the trials.

## Keywords

Neonatology · Randomized controlled trials · Risk of bias

## Abstract

**Background:** The introduction of Neonatology as a subspecialty in 1960 has stimulated an enormous amount of neonatal research. A large proportion of neonatal randomized-controlled trials (RCTs) have been included in the Cochrane

reviews, within which methodological quality or risk-of-bias (ROB) assessment is an integral feature. **Objectives:** We described the ROB profile of neonatal RCTs published since the 1950s. **Methods:** We analyzed individual studies within the Cochrane Neonatal reviews published up to December 2016. We extracted the reviewers' judgments on the ROB domains including random sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting. We evaluated blinding of personnel in trials in