

The WHO ACTION-I (Antenatal Corticosteroids for Improving Outcomes in preterm Newborns) Trial

Current Project Brief

Objectives and Background A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in hospitals in low-resource countries to improve newborn outcomes

Background and Objectives

Antenatal corticosteroids (ACS) have long been regarded as a cornerstone intervention in mitigating the adverse effects of preterm birth. However, there are several important limitations that restrict generalizability of current evidence to ACS use in low- and middle-income countries (LMICs). Furthermore, serious concerns regarding whether ACS are safe and/or effective in low-resource settings have been raised by the recent Antenatal Corticosteroids Trial (ACT).

The aim of this trial is to determine whether antenatal corticosteroids are safe and efficacious for women and newborns, when given to pregnant women with a live fetus/es at risk of imminent preterm birth from 26 weeks 0 days to 33 weeks 6 days gestation in hospitals in low-resource countries, for the prevention of neonatal deaths. Specifically, the trial aims to assess ACS safety and efficacy in hospitals where the WHO proposed ACS treatment criteria can reasonably be met in participating countries.

Primary objectives:

1. To compare the effect of dexamethasone to placebo on stillbirth and neonatal survival when given to pregnant women at risk of imminent preterm birth in hospitals in low resource countries.
2. To compare the effect of dexamethasone to placebo on possible maternal bacterial infections when given to pregnant women at risk of imminent preterm birth in hospitals in low resource countries.

Geographic location Bangladesh, India, Kenya, Nigeria, Pakistan

Main deliverables Safety and efficacy of dexamethasone when given to women at imminent risk of early preterm birth, at 26 weeks 0 days to 33 weeks 6 days

- Partners**
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