ACTION III: A multi-country, multi-centre, three-arm, parallel group, double-blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes

Date and name of person providing the information

Ayesha De Costa, 25 February 2021

Title of research project

ACTION III: A multi-country, multi-centre, three-arm, parallel group, double-blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes

Background

Antenatal corticosteroids in the early preterm period (<34 weeks of gestation) have been shown to clearly reduce mortality and morbidity in preterm neonates. However, there is no established evidence on the efficacy and safety of ACS use in late the preterm period (34-36 +6 weeks of gestation) on neonatal outcomes in low resource settings. While a large recent trial in the US showed a decrease in neonatal morbidity/mortality when steroids were given in the late preterm period, an earlier NIH supported Antenatal Corticosteroid Trial in resource-limited settings showed that this intervention may be ineffective or even harmful in resource-limited settings. This trial is need to provide evidence on the use of antenatal steroids in the late preterm period in resource limited setting and to thereby allow updating of the WHO guidelines on such use.

What are / were the main research questions addressed by this study?

To determine whether antenatal corticosteroids are safe and efficacious for women and newborns in resource-limited settings, when given to women with a live fetus/es at risk of imminent preterm birth from 34+0 to 36+5 weeks gestation in facilities for the prevention of neonatal mortality. A multi-country, multi-centre, three-arm, parallel, double-blind, placebo-controlled, randomized trial (6000 pregnant women).

Programmatic Implications of the study

There is no established evidence on the efficacy and safety of ACS use in late the preterm period on neonatal outcomes in low resource settings. WHO provides clear guidelines on the use of ACS in the early preterm period. This results of this trial will help to fill the gaps in the existing WHO guidance in the area of ACS use in the late preterm period.

What are the start and end dates for the data collection?

Sept 2021 - Dec 2023

Geographical location

South Asia and sub Saharan Africa

For further information, please contact:

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<table>
<thead>
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School of Medicine, University of Nairobi (Professor Zahida Qureshi, Professor Frederick Were) |
| Nigeria     | College of Medicine, University of Ibadan (Dr Adejumoke Idowu Ayede, Dr Bukola Adesina)  
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| Pakistan    | Aga Khan University, Karachi, (Dr Shabina Ariff) |

**Main external funders**

BMGF

**Link to an Internet site providing further details (e.g. clinical trial registration)**

None currently

**FOR COMPLETED PROJECTS ONLY:**

What were the main findings/conclusions?

Main scientific publication (URL)

Guidelines or other main WHO product (e.g. revised tool) derived from/informed by study

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