

Antenatal corticosteroids and small/sick newborn care interventions to Improve preterm birth outcomes in Bangladesh, Pakistan, Ethiopia and Nigeria

Submission date 28/11/2025	Recruitment status Recruiting	☐ Prospectively registered ☒ Protocol
Registration date 06/03/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 29/09/2026	Condition category Pregnancy and Childbirth	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Babies born too early (preterm) have a higher risk of dying or becoming seriously ill. Giving mothers a medicine called antenatal corticosteroids (ACS) before birth can help improve survival for these babies. While ACS is widely used in high-income countries, its safety and effectiveness in low-resource settings has been debated. This study aims to test a new approach to safely use ACS in countries with fewer resources, alongside improving care for mothers and newborns. The goal is to see if this approach reduces deaths among preterm babies.

Who can participate?

Women who give birth in selected hospitals and clinics in Bangladesh, Ethiopia, Nigeria, and Pakistan will be part of the study, along with their newborns. Health workers in these facilities will also take part in training and care improvements.

What does the study involve?

If you give birth in one of the study hospitals, your care will follow the hospital's usual practices or the new approach, depending on which group the hospital is in. The new approach includes better training for health workers, clear treatment guidelines, and improved care for preterm babies. You may receive ACS if you are at high risk of giving birth early and meet safety criteria. Your baby will receive standard newborn care, and extra support may be available for preterm babies.

What are the possible benefits and risks of participating?

The main benefit is that the care you and your baby receive may be improved, especially if you are at risk of preterm birth. This could help your baby survive and stay healthy. The risks are very low because the medicines and care used are recommended by the World Health Organization. However, ACS should only be given when it is safe, so health workers will check carefully before giving it.

Where is the study run from?

The study is being carried out in hospitals and clinics in Bangladesh, Ethiopia, Nigeria, and Pakistan.

When is the study starting and how long is it expected to run for?

The study will run for about 21 months. This includes 6 months of preparation, followed by 12 months of testing the new approach.

Who is funding the study?

The study is coordinated by the World Health Organization (WHO) and supported by international research partners.

Who is the main contact?

Dr Ayesha de Costa, deay@who.int

Contact information

Type(s)

Scientific, Public, Principal investigator

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

Scaling up safe use of antenatal corticosteroids and small/sick newborn care interventions to improve preterm birth outcomes in Bangladesh, Pakistan, Ethiopia and Nigeria - a parallel with baseline cluster randomised trial

Acronym

ACS IR cRCT

Study objectives

The goal of this cluster randomized trial is to test the impact of a package of healthcare interventions targeted at increasing safe ACS use, adequate childbirth care & adequate small /sick newborn care (Optimized ACS model) among women at risk of preterm birth and their newborns in low-resource settings.

The main question it aims to answer is:

Does the optimized ACS model reduce deaths among newborns born 28-<37 weeks gestation?

Researchers will compare control and intervention groups to see if there is a difference in preterm baby deaths (stillbirths & neonatal deaths) between the two groups after the optimized ACS model has been embedded in the intervention group.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/09/2025, WHO Ethics Review Committee (Avenue Appia 20, Geneva, 1211, Switzerland; +41 22 791 21 11; ercsec@who.int), ref: ERC0003768

Primary study design

Interventional

Study design

Interventional cluster randomized trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Preterm birth

Interventions

Intervention arm

ACS & Co-Interventions

Antenatal corticosteroids (ACS) for preterm birth, tocolysis & magnesium sulphate for neuroprotection.

Intervention includes training on: Right Woman: Identification and management of women at high risk of preterm birth, Right Treatment: ACS administration according to WHO guidelines Clinical protocols/job aids, diagnosis and treatment of women at high risk of preterm birth and administration of cointerventions (tocolysis & magnesium sulphate) according to clinical guidelines & Right Place: Promoting in-utero referral of preterm deliveries to high-level facilities.

Adequate childbirth care

Training of healthcare workers on appropriate monitoring of women during preterm labour and birth and strengthen recording practices, including introduction of the WHO labour care guide (LCG) adapted for preterm labour/birth.

Adequate preterm newborn care (Small/sick newborn care)

Training of healthcare workers on Essential newborn care at birth, KMC & breastfeeding (All facilities) and the eight domains of small and sick newborn care (SSNC) (Facilities with a SNCU /NICU). Provision of CPAP machines & pulse oximeters (SNCU/NICU). Provision of clinical protocols/job aids in Essential newborn care, Respiratory Support (CPAP), KMC, breastfeeding, alternative methods of feeding, hand hygiene, common problems, developmentally supportive care (DSC). Clinical onsite mentorship by experienced neonatologists in the SNCU in high level

facilities including monthly observations of clinical practice using the SSNC strengthening tool. Monthly audit and feedback meetings to facilitate feedback on progress based on tracking indicators within the eight domains of SSNC.

Community level intervention

Community level engagement with community health workers (CHWs) on the signs of preterm labour and importance of referring women to a high-level facility for delivery. Distribution of IEC materials for women & their families via CHWs on signs of preterm labour, where to seek care, KMC, breastfeeding & newborn danger signs.

Control arm

The clusters randomized to the control condition will be given basic support to promote safe ACS use. This includes the dissemination of WHO recommendations on ACS, adequate childbirth and newborn care to health workers. After randomization, control clusters will continue with usual care throughout the remainder of the trial period.

Randomization

32 clusters will be randomized in a 1:1 sequence (16 Control & 16 Intervention clusters). Covariate constrained randomisation by a statistical team at Birmingham University. This will be done for all clusters at the same time point, when the first cluster reaches week 16 of baseline. Each individual cluster's allocation will be disclosed when the cluster reaches week 16 of baseline.

There will be a 3 month transition phase for embedding the intervention (Data will not contribute to the trial). Then the intervention will continue in the intervention arms for 12 months. (Post transition phase)

Follow-up or data collection on the primary outcome will be for a total of 18 months for both the intervention & control arms (6 months at baseline and 12 months post transition phase).

Intervention Type

Mixed

Primary outcome(s)

Any baby death (stillbirth or neonatal death) among babies born ≥ 28 to < 37 weeks gestation by earliest available ultrasound, else in the absence of an ultrasound birthweight $\geq 1000\text{g}$ - $\leq 2000\text{g}$ measured using Assessment of mortality by a) Clinician in-hospital or b) mothers report at 28 days of life from birth to 28 days

Key secondary outcome(s)

Current key secondary outcomes as of 29/09/2026:

1. Preterm neonatal mortality is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life
2. Preterm stillbirth rate is measured using clinician assessment of birth status at the time of birth
3. Any baby death (early preterm) is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life
4. Early preterm neonatal mortality is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life
5. Any baby death is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

6. Neonatal mortality rate is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

7. Stillbirth rate is measured using clinician assessment of birth status at the time of birth

Safety Outcomes

1. Maternal Postpartum Infection: Proportion of all women who are readmitted to hospital for a suspected postpartum infection ≤ 28 days postpartum is measured using clinician assessment in-hospital and maternal report at the 28 day maternal & neonatal follow-up

2. Term Neonatal Mortality: Proportion of all liveborn term births that result in a neonatal death ≤ 28 days of life) is measured using clinician assessment in-hospital and maternal report at the 28 day maternal & neonatal follow-up

Previous key secondary outcomes:

1. Preterm neonatal mortality is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

2. Preterm stillbirth rate is measured using clinician assessment of birth status at the time of birth

3. Any baby death (early preterm) is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

4. Early preterm neonatal mortality is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

5. Any baby death is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

6. Neonatal mortality rate is measured using clinician assessment in-hospital and maternal report at 28-day follow-up from birth to day 28 of life

7. Stillbirth rate is measured using clinician assessment of birth status at the time of birth

Completion date

31/12/2027

Eligibility

Key inclusion criteria

All women and her newborn(s) that are delivered within the network of health facilities

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

0 Days

Upper age limit

55 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

A woman who does not consent to routine clinical data sharing or a neonatal and maternal follow-up on day 28 of life.

Date of first enrolment

07/12/2025

Date of final enrolment

31/12/2027

Locations

Countries of recruitment

Bangladesh

Ethiopia

Nigeria

Pakistan

Study participating centre

Projahnmo Research Foundation

Floor 7, House: 97A, Road: 25, Block # A, Banani

Dhaka

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Study participating centre

Center for Implementation Sciences (CIS) in Health, Aklilu Lemma Health Research Institute, Addis Ababa University

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Addis Ababa

Ethiopia

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Study participating centre

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Sponsor information

Organisation
World Health Organization

ROR
<https://ror.org/01f80g185>

Funder(s)

Funder type
Not defined

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from deay@who.int

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	23/09/2026	29/09/2026	No	No