

Implementation of an innovative approach to jump start simplified management of sick young infants with possible serious bacterial infection (PSBI) where referral is not feasible for potential scale-up

ACTRN12617001373369

Status	RECRUITING
Sponsor	World Health Organization
Enrollment	2,000 participants

Plain Language Summary

This study helps countries in Africa and Asia put into practice a World Health Organization (WHO) guideline for treating sick young babies (aged 0 to 59 days) with possible serious bacterial infection — such as pneumonia, sepsis, or meningitis — when it is not possible to get them to a hospital. These infections can be life-threatening in newborns. The guideline allows simplified antibiotic treatment near the baby's home when hospital referral is not possible. This implementation study aims to support health systems to adopt and scale up this simpler treatment approach.

You may be eligible if:

- You are the parent or carer of a young infant aged 0 to 59 days
- Your infant has signs of possible serious bacterial infection (such as fast breathing, fever, very low temperature, poor feeding, convulsions, or no movement)
- Your family is unable or unwilling to travel to a hospital for inpatient care

You may NOT be eligible if:

- There are no exclusion criteria listed for this study

Talk to your doctor or local health worker about whether this program might be right for your baby.

Key Eligibility Criteria

Inclusion (9)

- Young infants 0-59 days with PSBI and whose families do not accept or cannot access referral care for treatment. Clinical signs of PSBI are defined as:
 - fast breathing (respiratory rate greater and equal to 60 breaths/minute)
 - severe chest in-drawing
 - fever (temperature greater and equal to 38 °C)
 - hypothermia (temperature less than 35.5 °C)
- ... and 4 more (see full listing online)

Exclusion (1)

- none.

Locations (4 total)

Ethiopia
India
Nigeria
... and 1 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12617001373369>

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