

# Early feeding and kangaroo mother care to prevent infections in premature babies: a pilot study

<b>Submission date</b> 09/12/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/12/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2025	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Principal investigator, Public, Scientific

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## Additional identifiers

## Study information

**Scientific Title**  
Early exclusive enteral feeding with mother-incubator care to reduce neonatal sepsis in preterm infants: a randomized controlled pilot trial

**Study objectives**

**Primary objective:**

1. To assess whether early exclusive enteral feeding and maternal-incubator care reduces the incidence of neonatal sepsis in clinically stable preterm infants.

**Secondary objectives:**

1. To evaluate time to full enteral feeding
2. To assess weight gain on daily basis and duration of hospital stay
3. To measure maternal satisfaction and feasibility of total enteral feed and bedside care
4. To assess whether our study is cost effective

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 19/12/2025, Gajju Khan Medical College Swabi IREB (Shahmansoor, Shah Mansur, -, Pakistan; -; ireb@gkmcs.edu.pk), ref: IREB/GKMCS/082512450

**Primary study design**

Interventional

**Allocation**

Randomized controlled trial

**Masking**

Open (masking not used)

**Control**

Active

**Assignment**

Parallel

**Purpose**

Health services research, Prevention, Supportive care

**Study type(s)****Health condition(s) or problem(s) studied**

Early neonatal sepsis in preterm infants

**Interventions**

Intervention Group (Early EBM + Maternal-Incubator Care):

1. Initiate total nasogastric feeding with EBM within 3 hours of birth (60–80 mL/kg/day)
2. No IV fluids or antibiotics unless clinically indicated
3. Baby kept in incubator or warmer at mother's bedside
4. Encourage skin-to-skin contact and enable maternal access for feeding and milk expression
5. Oxygen via nasal cannula if needed
6. Blood sampling and culture on Day 3 of life
7. Terminate protocol if clinical deterioration or feeding intolerance occurs

Control Group (Standard NICU Care):

1. Standard NICU care will be provided in accordance with established guidelines (Start et al., 2023)
2. Admission to NICU with IV fluids and oxygen
3. Gradual feeding advancement with EBM
4. Routine investigations after 24 hours and as needed
5. Shift to KMC once baby is stable, on full feeds, and off oxygen

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Incidence of culture-positive or clinically diagnosed neonatal sepsis measured using Clinical signs (oxygen requirements, apnea, respiratory rate, heart rate, temperature instability, feeding intolerance) and Laboratory results (WBC, platelet count) at within the first 7 days

## **Key secondary outcome(s)**

Measured using patient records at end of stay:

1. Time to achieve full enteral feeding
2. Weight gain at discharge
3. Duration of hospital stay
4. Maternal satisfaction (via structured questionnaire)
5. Cost-effectiveness in terms of hospital stay, antibiotics use, incubator and NICU charges

## **Completion date**

31/03/2026

# **Eligibility**

## **Key inclusion criteria**

1. Gestational age >30 and <37 weeks
2. Birth weight >1000 g
3. Clinically stable at birth: Apgar  $\geq 7$  at 5 minutes or no need for invasive ventilation
4. Minimal respiratory support allowed: room air or oxygen  $\leq 2$  L/min via nasal cannula
5. No major congenital anomalies
6. Mother is stable and can take care for newborn

## **Healthy volunteers allowed**

No

## **Age group**

Neonate

## **Lower age limit**

0 days

## **Upper age limit**

1 days

**Sex**

All

**Total final enrolment**

100

**Key exclusion criteria**

1. Need for immediate resuscitation or mechanical ventilation
2. Clinical signs of sepsis at birth (e.g., temperature instability, poor perfusion, metabolic acidosis)
3. Prolonged rupture of membranes >18 hours with maternal chorioamnionitis or other high-risk infections
4. Maternal fever >38°C during labor or proven maternal sepsis
5. Major surgical conditions or gastrointestinal malformations
6. Reverse diastolic flow on prenatal ultrasound
7. Maternal death

**Date of first enrolment**

17/10/2025

**Date of final enrolment**

31/03/2026

**Locations****Countries of recruitment**

Pakistan

**Sponsor information****Organisation**

Bacha Khan Medical Complex MTI Swabi

**Funder(s)****Funder type****Funder Name**

Bacha Khan Medical Complex MTI Swabi

**Results and Publications****Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available