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

Submission date 09/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/12/2025	**Overall study status** Completed	
Last Edited 19/12/2025	**Condition category** Neonatal Diseases	

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 ≥7 at 5 minutes or no need for invasive ventilation
4. Minimal respiratory support allowed: room air or oxygen ≤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