

Impact of continuous Kangaroo Mother Care initiated immediately after birth (iKMC) on survival of newborns with birth weight between 1.0 to <1.8 kg: study protocol for a randomized controlled trial

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 Trials  BMC

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SUBJECT AREAS

Integrative & Complementary Medicine

KEYWORDS

Immediate Kangaroo Mother Care (iKMC), low birth weight babies, mortality, skin-to-skin contact, breastfeeding, mother-neonatal intensive care unit (M-NICU)

Abstract

Background: Globally about 15% of newborns are born with a low birth weight (LBW), as a result of preterm birth, intrauterine growth restriction or both. Up to 70% of neonatal deaths occur in this group within the first three days after birth. Kangaroo Mother Care (KMC) applied after stabilization of the infant, has shown to reduce mortality by 40% among hospitalized infants with birth weight <2.0 kg. In these studies, infants were randomized and KMC initiated after about three days of age, by when the majority of neonatal deaths would have already occurred. The aim of this trial is to evaluate the safety and efficacy of continuous KMC initiated as soon as possible after birth compared to the current recommendation of initiating continuous KMC after stabilization in neonates with birth weight between 1.0 and <1.8 kg. **Methods:** This randomized controlled trial is being conducted in tertiary care hospitals in five low- and middle-income countries (LMICs) in South Asia and Sub-Saharan Africa. All pregnant women admitted in these hospitals for childbirth are being pre-screened. After delivery, all neonates with birth weight between 1.0 and <1.8 kg are being screened for enrolment. Eligible infants are randomized into intervention and control groups. The intervention consists of continuous skin-to-skin contact initiated as soon as possible after birth, promotion and support for early exclusive breastfeeding, and provision of health care for mother and baby with as little separation as possible. This efficacy trial will primarily evaluate the impact of KMC started immediately after birth on neonatal death (between enrolment and 72 hours of age, and deaths between enrolment and 28 days of age), and other key outcomes.

Discussion : This is the first large multi-country trial studying immediate KMC in low- and middle-income countries. Implementation of this intervention has already resulted in an important enhancement of the paradigm shift in LMIC settings in which mothers are not separated from their baby in the neonatal intensive care units (NICU). The findings of this trial will not only have future global implications on how the LBW newborns are cared for immediately after birth, but also for the dissemination of designing NICUs according to the “Mother-Newborn Intensive Care Unit (M-NICU) model.”

Trial registration : Clinical Trials Registry India (CTRI)- CTRI/2018/08/01536 (retrospectively

registered); Australian New Zealand Clinical Trials Registry (ANZCTR) - ACTRN12618001880235 (retrospectively registered). <https://anzctr.org.au/ACTRN12618001880235.aspx> Funding: The study is funded by a grant from the Bill and Melinda Gates Foundation to the World Health Organization (Grant agreement OPP1151718) Keywords : Immediate Kangaroo Mother Care (iKMC), low birth weight babies, mortality, skin-to-skin contact, breastfeeding, mother-neonatal intensive care unit (M-NICU)

Full Text

Due to technical limitations, full-text HTML conversion of this manuscript could not be completed.

However, the manuscript can be downloaded and accessed as a PDF.

Figures

		STUDY PERIOD						
	Pre-enrolment	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT**	Day of Hospital admission (for childbirth)	At birth	Within 2 hours of birth	Stay in NICU (until transfer out to KMC ward)		Stay in KMC ward (until discharge from hospital)	After hospital discharge until day 29	Day 29 after birth
				12 h of age	24 h of age	Every 12 h until transfer out of NICU	Every 12 h until discharge	
ENROLMENT:								
Pre-screening	X							
Informed consent	X							
Screening		X						
Confirmation of consent		X						
Allocation			X					
INTERVENTION:								
Intervention: Immediate KMC				X	X	X		
Control:								
Co intervention for both intervention and control groups:								
Minimum care package		X	X	X	X	X	X	
Continuous KMC after stabilization							X	X
ASSESSMENTS:								
Mortality				X	X	X	X	X
Breastfeeding				X	X	X	X	X
Clinical sepsis				X	X	X	X	
Hypothermia				X	X	X	X	
Hypoglycemia				X	X			
Clinical Stabilization				X	X	X	X	
Maternal satisfaction							X (at discharge)	
Maternal depression								X

Figure 1

Schedule of enrolment, interventions, and assessments for the IKMC Study.

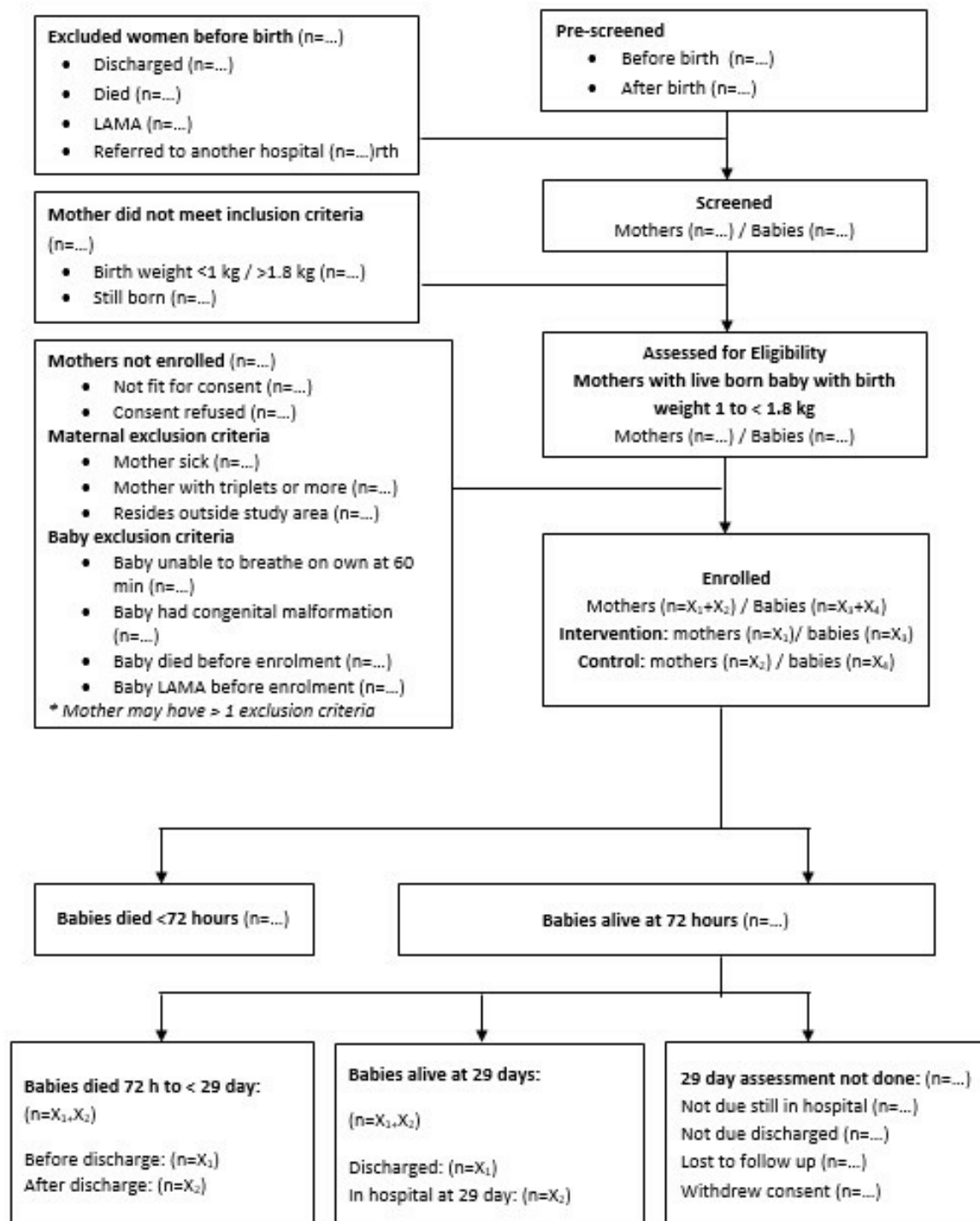


Figure 2

Structure of the Study Flow Chart

Supplementary Files

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