

## Clinical Trial Details (PDF Generation Date :- Thu, 16 Sep 2021 19:46:56 GMT)

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| **CTRI Number** | CTRI/2018/08/015369 [Registered on: 17/08/2018] - **Trial Registered Retrospectively** |
| **Last Modified On** | 23/04/2020 |
| **Post Graduate Thesis** | No |
| **Type of Trial** | Interventional |
| **Type of Study** | Process of Care Changes |
| **Study Design** | Randomized, Parallel Group Trial |
| **Public Title of Study** | Immediate skin to skin contact of the baby with mother or the surrogate |
| **Scientific Title of Study** | A multi-country randomized clinical trial to evaluate the impact of continuous KMC initiated immediately after birth compared to KMC initiated after stabilization in newborns with birth weight 1.0 to less than 1.8 kg on their survival in low-resource settings |

**Secondary IDs if Any**

| Secondary ID | Identifier |
|---|---|
| NIL | NIL |

**Details of Principal Investigator or overall Trial Coordinator (multi-center study)**

| Details of Principal Investigator | |
|---|---|
| **Name** | Dr Harish Chellani |
| **Designation** | Consultant (Professor) & HOD |
| **Affiliation** | Vardhman Mahavir Medical College & Safdarjung Hospital |
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**Details Contact Person (Scientific Query)**

| Details Contact Person (Scientific Query) | |
|---|---|
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**Source of Monetary or Material Support**

| Source of Monetary or Material Support |
|---|
| > Bill & Melinda Gates Foundation, 500 Fifth Avenue North Seattle, WA 98109 |

**Primary Sponsor**

| Primary Sponsor Details | |
|---|---|
| **Name** | World Health Organization |
| **Address** | Avenue Appia 20 CH-1211 Geneva 27 Switzerland |
| **Type of Sponsor** | Other [International public health Agency] |

**Details of Secondary Sponsor**

| Name | Address |
|---|---|
| NIL | NIL |

**Countries of Recruitment**

| List of Countries |
|---|
| Ghana |
| India |
| Malawi |
| Nigeria |
| Other |

**Sites of Study**

| Name of Principal Investigator | Name of Site | Site Address | Phone/Fax/Email |
|---|---|---|---|
| Dr Harish Chellani | Vardhman Mahavir Medical College & Safdarjung Hospital | Department of Pediatrics Vardhman Mahavir Medical College & Safdarjung Hospital New Delhi 110029 South DELHI | 91-11-26730241<br><br>chellaniharish@gmail.com |

**Details of Ethics Committee**

| Name of Committee | Approval Status | Date of Approval | Is Independent Ethics Committee? |
|---|---|---|---|
| Institute Ethics Committee VMMC & Safdarjung Hospital New Delhi | Approved | 10/08/2017 | No |

**Regulatory Clearance Status from DCGI**

| Status | Date |
|---|---|
| Not Applicable | No Date Specified |

**Health Condition / Problems Studied**

| Health Type | Condition |
|---|---|
| Patients | Newborn affected by maternal conditions that may be unrelated to present pregnancy |

**Intervention / Comparator Agent**

| Type | Name | Details |
|---|---|---|
| Comparator Agent | KMC after stabilisation | skin-to-skin contact/ kangaroo mother care initiated after stabilisation of baby with mother or surrogate |
| Intervention | Immediate KMC | continuous skin-to-skin contact/ kangaroo mother care initiated immediately after birth with mother or surrogate |

**Inclusion Criteria**

| Inclusion Criteria | |
|---|---|
| **Age From** | 1.00 Day(s) |
| **Age To** | 1.00 Day(s) |



| | |
|---|---|
| **Gender** | Both |
| **Details** | All babies born alive in the participating hospitals, with birth weight between 1.0 to less then 1.8 kg, regardless of their gestational age, are eligible for participation in this trial with their mothers. The mother-baby pair is still eligible if the mode of delivery is caesarean section, if the babies are twins or if the mother experiences some complications during labour and delivery that are expected to resolve within 3 days. |

**Exclusion Criteria**

| **Exclusion Criteria** | |
|---|---|
| **Details** | (i) the mother is younger than 15 years of age<br>(ii) the mother (or her guardian in case mother is a minor aged 15-17 years) is unable or unwilling to provide consent;<br>(iii) the mother is unlikely to be able to provide KMC for the first 3 days after birth, e.g. she has eclampsia, shock or has undergone major surgery;<br>(iv) the baby is unable to breathe spontaneously within 1 hour of birth;<br>(v) multiple pregnancy: triplets or more;<br>(vi) the baby has a congenital malformation that interferes with the intervention, or the intervention interferes with the required care for the congenital malformation;<br>(vii) the place of residence is not a part of the defined study area (the study area will be defined to make 28-day follow up home visit feasible)<br>(viii) If for any reason the mother baby pair cannot be enrolled within 2 hours of birth of the baby. |

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|---|---|
| **Method of Generating Random Sequence** | Computer generated randomization |
| **Method of Concealment** | Pre-numbered or coded identical Containers |
| **Blinding/Masking** | Open Label |

**Primary Outcome**

| Outcome | Timepoints |
|---|---|
| Mortality | (i) mortality between enrolment and 72 hours of age, and<br>(ii) mortality between enrolment and 28 days of age. |

**Secondary Outcome**

| Outcome | Timepoints |
|---|---|
| time to stabilization, hypothermia and risk of infection during hospital stay, time to hospital discharge, exclusive breastfeeding at the end of neonatal period, maternal satisfaction with care received in the hospital, and maternal depression,Time to being fully breastfed, suspected sepsis (Early onset: less than 72 hours of age, Late onset more than 72 hours of age), Probable sepsis, early or late onset, Hypoglycemia, Death in babies not enrolled in the study up to 72 hours of age. | None |

| | |
|---|---|
| **Target Sample Size** | **Total Sample Size=**4200<br>**Sample Size from India=**1680<br>**Final Enrollment numbers achieved (Total)=**3211<br>**Final Enrollment numbers achieved (India)=**1377 |
| **Phase of Trial** | N/A |
| **Date of First** | 01/12/2017 |



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|---|---|
| **Enrollment (India)** | |
| **Date of First Enrollment (Global)** | 01/12/2017 |
| **Estimated Duration of Trial** | **Years=**2<br>**Months=**0<br>**Days=**0 |
| **Recruitment Status of Trial (Global)** | Completed |
| **Recruitment Status of Trial (India)** | Completed |
| **Publication Details** | Study protocol published in BMC DOI: doi.org/10.1186/s13063-020-4101-1 |
| **Brief Summary** | Aim and hypothesis: The aim of this trial is to evaluate the safety and efficacy of continuous KMC initiated immediately after birth for neonates' with birth weight from 1.0 to <1.8 kg compared to the current recommendation of initiating continuous KMC after stabilization. The main hypothesis is that neonates with birth weight 1.0 to <1.8 kg, who are exposed to continuous KMC initiated immediately after birth, will experience a reduced risk of death compared to neonates in whom KMC is initiated after stabilization.<br><br>Methods:<br><br>Study design and setting: The study will be a multi-country, multi-centre, randomized controlled trial. The study will be conducted in tertiary care hospitals in five low- and middle-income countries in Asia and Sub-Saharan Africa, namely Ghana, India, Malawi, Nigeria and Tanzania.<br><br>Sample size: The sample size for comparison of risk of death in intervention and control groups (21.1% compared with 16.8%) is 2080 per group, requiring a total of about 4200 neonates. Based on the number of neonates born in the selected hospitals, enrolment can be completed in about two years. For sample size calculation, we have conservatively assumed that the intervention group will have 20% lower mortality compared with control group.<br><br>Population: The study population will be neonates born within the participating hospitals with birth weight between 1.0 and <1.8 kg, regardless of their gestational age. Babies will still be eligible if they are twins, or are born through caesarean section or if their mothers had delivery complications that are expected to resolve within 3 days, so that they will be able to move to the neonatal unit within 3 days of birth to provide KMC to the neonate. Triplets or quadruplets, or babies who are unable to breathe spontaneously within the first hour after birth, or who have congenital malformations that interfere with the intervention, or babies whose mothers are not able to give consent or refuse to participate in the study, or who live outside a defined study area will be excluded from the study. WHO statistician had prepared a computer-generated block randomization list with variable block size, stratified by site and by birth weight. The strata by birth weight will be from 1.0 to less than 1.5kg and from 1.5 to less than 1.8kg.<br><br>Intervention: The intervention has three main components (i) continuous skin-to-skin contact initiated immediately after birth with mother, aiming for at least 20 hours per day; (iii) promotion and support for early exclusive breastfeeding, and (iii) provision of health care for mother and baby with as little separation as possible. If the mother cannot provide continuous KMC for any reason, she will be asked to choose a surrogate to provide skin-to-skin contact. The intervention group will be provided continuous KMC before stabilization in the neonatal special care unit, and continuous KMC after stabilization in the KMC ward. |



Comparator: Neonates randomized to the control group will receive conventional care, for which the mother and baby are separated, until the baby is clinically stable. Short sessions of KMC will be started in neonates randomized to the control group when the baby is recovering but is still in the special newborn care unit. Continuous KMC will be initiated after the baby is stable and is transferred to the KMC ward.

Care in both intervention and control groups: All neonates enrolled in this study will receive the WHO minimum package of care for small babies. This care will be the same for the intervention and control groups, except that babies randomized to intervention will be given continuous KMC with mothers or surrogates in the neonatal special care unit, but babies allocated to control group will receive care in incubators, radiant warmers or cots while they are unstable.

Outcomes: The primary outcomes of this study will be (i) mortality between enrolment and 72 hours of age, and (ii) mortality between enrolment and 28 days of age. Secondary outcomes will be time to stabilization, hypothermia and risk of infection during hospital stay, time to hospital discharge, exclusive breastfeeding at the end of neonatal period, maternal satisfaction with care received in the hospital, and maternal depression. We will also monitor mortality in the first 72 hours of life among all live births with birth weight between 1.0 and <1.8 kg in participating hospitals, irrespective of enrolment in the trial.