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To assess the feasibility of use of Kangaroo Mother Care for transport of neonates in Sub-Saharan Africa

Submission date
28/08/2024

Recruitment status
No longer recruiting

Registration date
02/09/2024

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Newborns delivered in the rural and peripheral centres in most Sub-Saharan African countries and transported to the specialised centres usually in the arms of the parents and caregivers and public transport due to the unavailability of dedicated ambulances. A number of these babies arrive cold and unstable which affects their care and survival.
This study aims to assess the feasibility of performing a larger study which compares the outcomes of babies who are transported using kangaroo mother care and those who are transported through the current process in the arms of caregivers from the peripheral birthing centres to a specialised neonatal unit in Sub-Saharan Africa using the available mode of transport

Who can participate?
Preterm and low birth weight (< 2.5kg) less than 28 days old who are born in the periphery and have to be transported to the specialised centre for continued care

What does the study involve?
Babies (premature and small for age) to be transported will be identified from 8 different hospital sites. Healthcare workers involved in the study will be trained on the study before the start.
One group of babies will be transported by Kangaroo mother care after initial stabilization and feeding using Kangaroo mother care and the other group of babies will be transported using the already existing process.
Parents and caregivers would use the existing mode of transport without this being altered by the study.
If a health worker is available to accompany the babies, they will be responsible for monitoring and recording the vital signs during the transport, otherwise, the caregiver is advised to closely keep an eye on the breathing, movements and colour of the baby.

What are the possible benefits and risks of participating?
Possible benefits include babies transported by kangaroo mother care arriving with a normal body temperature which will improve their chances of survival

Where is the study run from?
Cape Coast Teaching Hospital (Ghana)

When is the study starting and how long is it expected to run for
December 2020 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main Contact?
Dr Emmanuel Okai, e.okai@uccsms.edu.gh

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Use of Kangaroo Mother Care in the transfer of preterm and low birth weight infants: a two-arm non-randomized controlled cluster feasibility study of neonatal transport in Cape Coast, Ghana

Acronym
FUKMC

Study objectives
In the absence of an organised transport system, alongside the limited availability of basic systems of transport, and increasing situations where parents must pay out of pocket for transfer, many newborns particularly preterm and low birth weight (LBW) are transported by less safe methods to higher centres of care. In developing countries Exploring the safe use of Kangaroo Mother Care (KMC) in the transfer of these neonates might go a long way towards reducing the burden of neonatal mortality and morbidity in resource-constrained settings

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/07/2021, Cape Coast Teaching Hospital Ethical Review Committee (Cape Coast Teaching Hospital, Cape Coast, CC-070-9967, Ghana; +233 21-340102-14; info@ccthghana.org), ref: CCTHERC/EC/2021 (053)

Study design
Two arm non-randomized controlled cluster study

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Improving outcomes of transported preterm and low-birth-weight neonates in Sub-saharan Africa

Interventions
Four primary care/ maternity units with the highest referral/transfer to the neonatal unit of Cape Coast Teaching Hospital (CCTH) were initially recruited following a review of the admission-discharge records over the past 2 years and a 2-month piloting of a designed proforma. Two of these sites were designated as intervention sites and the other two, as control sites with consideration given to optimal balance for socioeconomic status, the size of the maternity unit, ethnic mix, and distance from the neonatal unit in CCTH. Two additional maternity units were added to each arm of the study, 6 months into the study to make up for participant losses. All neonates enrolled in the study had a period of initial stabilisation pre-transfer during which they received conventional care.

Conventional care (Control group and KMC group)
Conventional care for neonates starts in the delivery room, where the nurse/midwife receives the neonate after delivery, quickly dries and wraps in a towel and provides the necessary resuscitation as prescribed by the Helping Babies Breathe algorithm. A physical examination to check for any anatomical anomalies was performed by the receiving health worker and babies were given vitamin K injection intramuscularly and tetracycline ophthalmic ointment applied. Vital signs (temperature, heart rate, respiratory rate, and oxygen saturation) were checked by the nurse and feeding either at the breast or using expressed breastmilk via cup or nasogastric

tube provided. Participants recruited from control sites received conventional care and their babies were transferred to CCTH using the current established mode of transfer.

Kangaroo Mother Care group (Intervention group)
Neonates at the intervention sites received the same initial stabilization and conventional care as neonates at the control sites. Participants (mother-baby pairs) who were identified by trained health workers at the intervention sites for transfer and who gave consent for participation in the study, were taught the appropriate procedure for KMC and the babies were transferred to the special care baby unit, CCTH with the intervention. The intervention sites assessed women or caregiver's confidence and competence in using KMC and any identified issues were improved before the transfer.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Survival and live discharge of preterm and low birthweight neonates measured using data collected from a review of patient records when the babies were eventually discharged from the Unit

Key secondary outcome(s))
The following secondary outcome variables on the impact of the intervention on improvement in morbidity were measured using a proforma questionnaire for the data collection and populated upon admission of the baby to Cape Coast:
1. Thermal stability (hypothermia)
2. Glucose control (hypoglycaemia)
3. Oxygen saturation (hypoxia)

The qualitative component of the study to assess the acceptability of the use of KMC was measured using semi-structured interviews after the arrival of the babies in Cape Coast

Completion date
30/05/2023

Eligibility

Key inclusion criteria
1. Newborns <2500 grams and/or 28 to 37 weeks gestation at birth
2. Newborns less than 28 days old
3. Apgar score of at least 5 in the first and fifth minutes of life
4. Not requiring any ventilatory support, intravenous fluids, or vasopressors
5. Participants who provide informed consent to take part in the study. Fathers or family members willing to participate in situations where the mother was medically unwell for the transfer.

Participant type(s)
Health professional, Population, Service user

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
28 days

Sex
All

Total final enrolment
77

Key exclusion criteria
1. Apgar score of less than 5 at 10 minutes of age
2. Term neonates or neonates >28 days of age
3. Preterm/LBW requiring prolonged resuscitation and oxygen therapy after 4 hours of life
4. Newborns with major congenital malformations
5. Hypoxic ischaemic encephalopathy/prenatal asphyxia
6. Mothers with postnatal complications who were unable to give consent and had no dedicated family member to consent for inclusion in the study

Date of first enrolment
01/08/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
Ghana

Study participating centre
Cape Coast Teaching Hospital
Cape Coast
Cape coast
Ghana
CC-070-9967

Sponsor information

Organisation

University of Cape Coast

ROR
https://ror.org/0492nfe34

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (Emmanuel Okai, e.okai@uccsms.edu.gh)

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/12/2024	30/12/2024	Yes	No
Participant information sheet			30/08/2024	No	Yes
Participant information sheet			30/08/2024	No	Yes
Participant information sheet			30/08/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			30/08/2024	No	No