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# The effectiveness of knee-chest-flexion maneuver in reducing respiratory distress in elective cesarean section newborns: protocol for a randomized controlled trial

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ABSTRACT

*Background:* Cesarean section (CS) birth is a risk factor for respiratory distress (RD) in term and near-term infants, which has been steadily increasing globally. The absence of labor has been linked to RD resulting from planned CS births. Uterine contractions contribute to the dorsiflexed position of the fetus which increases abdominal and trans-pulmonary pressure resulting in lung liquid loss via nose and mouth. We recently demonstrated the feasibility and safety of applying Knee-to-Chest Flexion (KCF), where the newborn was placed in a flexed "fetal" position, leading to lung liquid expulsion.

In this trial, the effectiveness of the KCF maneuver in reducing RD in infants delivered by planned CS will be examined.

*Methods:* This will be a randomized controlled two-arm trial in which 521 infants born by elective CS at 37–42 weeks gestational age will be randomized, in 1:1 ratio, to receive either a KCF maneuver or standard care, before being followed up for at least 24 h. The study will be conducted at Kilimanjaro Christian Medical Centre hospital and Mawenzi Regional Referral hospital in Tanzania. Consent will be sought from mothers scheduled for elective CS prior to randomization. The primary outcome is the occurrence of respiratory distress. Secondary outcome is admission to Neonatal Care Unit.

*Discussion:* This trial investigates KCF maneuver as an intervention to facilitate lung liquid clearance in newborns born by planned CS. It is anticipated to produce evidence of KCF as a highly cost effective innovation that will improve neonatal outcomes in clinical settings.

**Trial registration number:** ClinicalTrials.gov: NCT06270823

## 1. Introduction

### *1.1. Background and rationale*

Respiratory distress (RD) in newborns is frequently linked with preterm birth, but it is also common among infants born at or near term. [1] Premature newborns commonly experience classical respiratory distress syndrome, which is due to immature lungs resulting in surfactant deficiency and large air/blood gas barriers. In contrast, term/near-term infants who experience respiratory distress and are admitted into the neonatal intensive care unit (NICU), are commonly diagnosed with transient tachypnea of the newborn (TTN). [2] However, the true clinical burden of respiratory distress in term/near-term infants is difficult to truly quantify, as its definition is not always consistent among studies.

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In the clinical context, TTN is often diagnosed retrospectively in newborns who do not develop more severe respiratory distress (respiratory distress syndrome (RDS).

One of the major risk factors for developing respiratory distress in term/near-term infants is birth via elective cesarean section (CS). [3] CS is an increasingly common mode of delivery, with an incidence that almost doubled from 12 % in 2000 to 21 % in 2015 for all births worldwide, although there is much interregional variability. [4,5] The form of RD commonly associated with CS usually occurs in otherwise healthy babies and is considered to be a self-limiting complication that occurs within a few hours to days of birth and was thought to be due to delayed clearance of airway liquid or delayed transition. [6,7] Nevertheless, respiratory support often results in unexpected admission to intensive care units and can even lead to persistent pulmonary hypertension (PPHN) and/or chronic lung disease. [3,8] TTN is also associated with asthma, bronchiolitis, and other wheezing syndromes later in life. [9] In high-income settings, approximately 1 in 10 infants born after elective cesarean section need to be admitted to the intensive care unit for life-sustaining respiratory support. In low- and middle-income settings, where neonatal intensive care resources are limited, a considerable proportion of babies in need of respiratory support do not survive.

While the lungs are filled with liquid antenatally, airway liquid clearance and aeration are pivotal for adapting to life after birth. Airway liquid clearance can begin before birth, particularly during labor when airway liquid expulsion can occur in response to uterine contractions. After birth, the trans-pulmonary pressures generated by breathing are responsible for airway liquid clearance, but this involves reabsorbing the liquid into lung tissue. [10] During labor, uterine contractions contribute to flexion of the fetus, which increases abdominal and transpulmonary pressure. This elevates the diaphragm and increases intrathoracic pressures resulting in lung liquid loss via the nose and mouth, thereby avoiding the need to reabsorb this liquid into lung tissue after birth. Birth in the absence of uterine contractions means that infants will have much greater volumes of airway liquid when they start breathing, which must be cleared into lung tissue. [11,12] There is now strong physiological evidence that respiratory distress (TTN, RDS, and PPHN) after elective cesarean section is caused by the greater volume of airway liquid present at birth. [13]

There is now substantial physiological evidence to indicate that respiratory distress in near term infants likely results from having too much airway liquid at birth. As a result, this liquid must be cleared into lung tissue, causing pulmonary oedema and poorer lung function in the immediate newborn period (Fig. 1). [13,14] Importantly, physiological investigations have identified the following mechanistic explanations for classical symptoms of TTN and RDS: rapid and labored breathing, grunting and poorer oxygenation. The finding that newborns with elevated airway liquid volumes at birth have greater difficulty maintaining functional residual capacity (FRC) between breaths suggests that airway liquid re-entry between breaths plays a major role in poor lung function in term newborns with TTN/RDS. [13–15] As the liquid is cleared from the airways into lung tissue, a larger volume creates greater oedema and positive pressure in the interstitial tissue space, which reduces respiratory function. A larger volume of liquid in the interstitial tissue space increases the tendency for liquid to re-enter the airways, increases chest wall expansion and flattens the diaphragm. This restricts the gas exchange surface area and reduces the infant's ability to inspire, forcing it to increase its breathing rate to ventilate the lung. Additionally, after entering the interstitial lung tissue, airway liquid forms perivascular fluid cuffs around blood vessels. [16] As a result, greater airway liquid volumes may increase the pressure within these cuffs, thereby compressing pulmonary vessels and reducing pulmonary blood flow, resulting in excessive PPHN. [13]

The uterine contractions that occur during labor are absent when infants are born by elective cesarean section without labour. During labor, large volumes of airway liquid can be lost through the nose and mouth due to increased intrathoracic pressure generated by increased

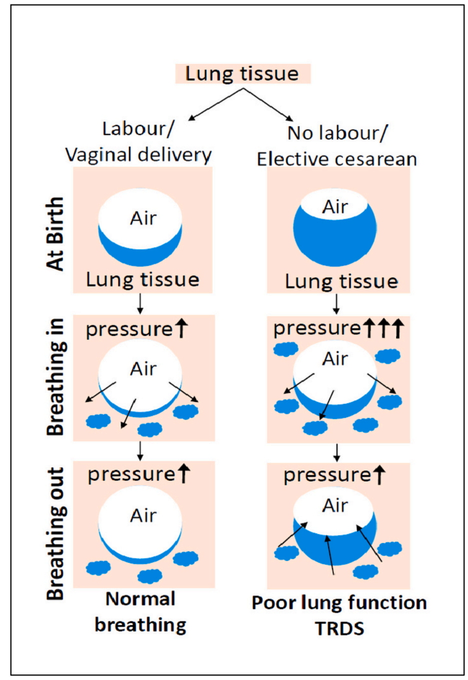


**Fig. 1.** Difference in airway liquid volume in babies born by vaginally with labor (left) or by cesarean section without labor (right).

fetal spinal flexion during intrauterine contractions, especially in the absence of amniotic fluid. [17–19] Considering that an elevated lung liquid volume is the main problem, we postulate that reducing this volume has the potential to decrease the occurrence of respiratory distress in infants born after elective cesarean section. The increase in spinal flexion caused by uterine contraction, which leads to lung liquid expulsion, can be replicated by performing a knee-to-chest flexion (KCF), whereby the infant is held in dorso-ventrally flexed position immediately after birth. We hypothesize that, this simple method for reducing excess airway liquid in infants born after elective CS, before large liquid volumes can cause respiratory problems, has the potential to decrease the burden of respiratory problems in this group of infants.

We recently performed a feasibility study at Leiden University Medical Centre in the Netherlands to test whether performing a KCF maneuver is feasible directly at birth in infants born after elective CS and whether this leads to visible clearance of excess lung liquid. Using a go-pro camera, all maneuvers were recorded and evaluated. We observed that KCF could be performed in most infants, was safe and the caused the visible release of lung liquid via the nose and mouth in more than one-third of infants. [20]

If this simple intervention can improve neonatal outcomes, KCF will undoubtedly be an extremely cost-effective health care innovation. The maneuver is easy to perform for any clinician undertaking a cesarean section delivery. KCF should be performed in accordance with standard gentle care and is likely to be entirely harmless. This approach may even contribute to clinicians performing delayed cord clamping, which is now considered the best practice. These advantages (easy-to-teach, no cost, no harm) are relevant across all settings but may be particularly appealing in low-income settings, where neonatal follow-up and access to neonatal intensive care are often either limited or not possible.

## 2. Methods

### *2.1. Aim of the trial*

To test whether performing a knee-to-chest flexion (KCF) maneuver directly after elective CS will decrease the incidence of respiratory distress in term infants compared to standard care.

### 2.2. Trial design

This will be an open-label randomized controlled two-arm trial in which infants born by planned CS will be randomized in a 1:1 ratio to the KCF and standard care arms and followed up for 24 h after birth. Fig. 2 shows the flowchart of events. (Fig. 2).

### 2.3. Study setting

This study will be conducted at Kilimanjaro Tanzania, in obstetrics and gynaecology departments of Kilimanjaro Christian Medical Centre (KCMC) zonal referral hospital and Mawenzi regional referral hospital.

### 2.4. Eligibility criteria

The study population will be term infants born by elective CS at the study sites. To be included in the study, participants must be scheduled for a CS at term (37–42 weeks gestational age).

Participants will be considered not eligible for enrollment in the trial if they have at least one of the following criteria;

- Significant congenital malformations influencing cardiopulmonary transition.
- Infants where immediate cord clamping is needed.
- When spontaneous contractions occur before the CS is performed.
- Infants of mothers with diabetes mellitus, Gestational diabetes, chronic hypertension and pregnancy induced hypertension

### 2.5. Treatment of subjects

#### 2.5.1. Intervention arm

Immediately after infants are extracted from the uterus, a KCF will be performed before vigorous breathing of the infant commences. The obstetrician will place one hand at the neck and shoulder of the baby and

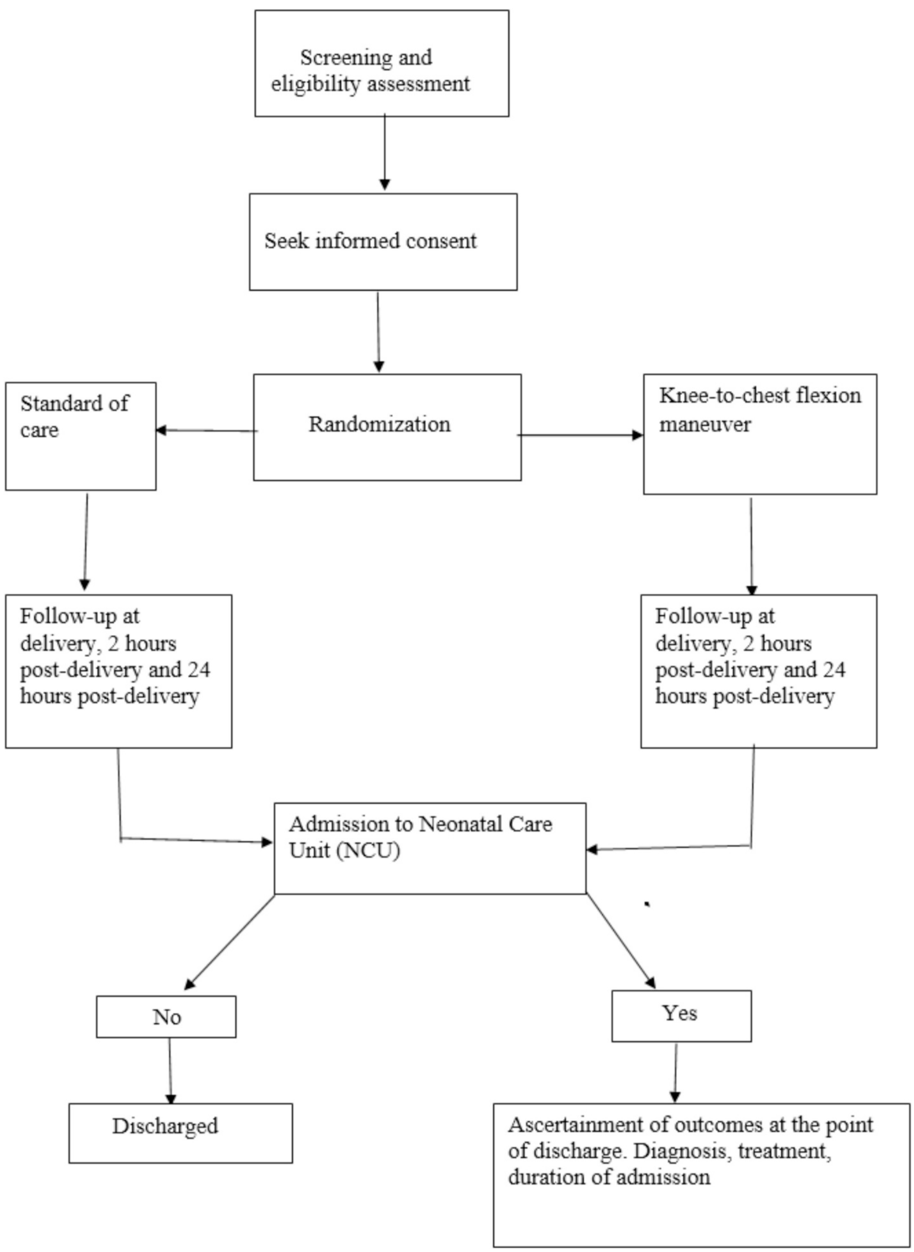


**Fig. 2.** Flow chart of events.

gently bend the infant into a dorsiflexed position while also bending the hips and knees against the abdomen and chest (to the fetal position). This holding position will continue for 30 s, while compression of the umbilical cord will be avoided to maintain undisturbed umbilical circulation to and from the infant during KCF. The technique used will be similar to the position at which an infant is held during lumbar puncture. (Fig. 3).

Infants in the intervention arm will receive KCF directly after birth by elective CS. KCF will be performed before the infant has taken its first breath. A small proportion of infants will breathe instantaneously and vigorously after they leave the uterus. Given that KCF is unlikely to be effective in these infants, KCF will not be performed to avoid interfering with the infant's vigorous breathing effort. With the exception of KCF, infants will receive routine care, i.e., they are covered and kept warm and later given to their mothers. There are no co-interventions. Thereafter, they will be followed up for 24 h. The babies will be examined at birth, at 2 h and 24 h post-delivery. Monitoring will be done clinically taking the respiratory rate, heart rate, oxygen saturation and signs of respiratory distress i.e. tachypnea (>60breaths/min), chest retraction, nasal flaring, grunting or cyanosis.

#### 2.5.2. *Control arm*

Infants in the control arm will receive standard care as will any other newborn delivered by CS i.e., after delivery and cord clamping, they will be dried, covered and kept warm and later given to their mothers to nurse. Thereafter, they will be followed up for 24 h as described in intervention arm. This means apart from KCF maneuver, these infants will receive the same standard of care as those in the intervention arm including cord clamping time which will be recorded for both arms.

### 2.6. *Outcomes*

#### 2.6.1. *Primary outcome*

The primary outcome is the occurrence of respiratory distress. Respiratory distress is defined as presentation of one or more signs of respiratory distress i.e. tachypnea (>60breaths/min), chest retraction, nasal flaring, grunting or cyanosis.

Respiratory distress will be measured in three categories;

**Mild respiratory distress (delayed transition);** at least one or more of the signs of respiratory distress lasting for two hours after delivery.

**Moderate respiratory distress;** at least one or more of the signs of respiratory distress lasting for more than two hours but resolves within 24 h, for which admission to Neonatal Care Unit (NCU) is needed.

**Severe respiratory distress;** at least one or more of the signs of respiratory distress lasting for more than 24 h, for which admission to Neonatal Care Unit (NCU) is needed.


**Fig. 3.** Knee-to-Chest maneuver position.

#### 2.6.2. *Secondary outcomes*

How often KCF was adequately performed.

The occurrence of a KCF where expulsion of lung liquid during KCF is observed.

Occurrence of an adverse event.

All-cause mortality.

### 2.7. *Other study parameters*

The following baseline characteristics will be collected: gestational age, birth weight, sex, presentation, complications during pregnancy, use of corticosteroids (started therapy, completed therapy), Apgar score at 1, 5 and 10 min after birth.

### 2.8. *Participant timeline*

Participants will be followed up in the study for at least 24 h (Table 1). After birth, infants will be assessed at three points, 10th minute, at 2 h and 24 h. Follow-up will continue for each infant who will be admitted to neonatal care unit to the point of discharge.

### 2.9. *Sample size*

There is a large variation in the reported incidence of respiratory distress after CS, as different settings and criteria/definitions have been used. We estimated that the current occurrence of respiratory distress after elective CS was 15 %. To detect an absolute decrease from 15 % to 7 %, with a power of 80 % and an α error of 5 % (two-tailed test), 474 infants were needed. Taking into account that KCF cannot be performed in 10 % of infants, we will include a total of 521 infants.

### 2.10. *Recruitment*

Prior to the start of the study, all obstetricians who perform CS will be trained in executing a standardized KCF.

Parents will be approached for participation during antenatal period. They will be informed of what they can expect the obstetrician will do during the CS. Researchers and/or doctors of the obstetric department will provide the information and informed consent form. After what is considered a reasonable time by parents to read, discuss and process the information, parents are asked for study participation.

**Table 1**
SPIRIT figure for study procedures and events.

| | STUDY PERIOD | | | | |
|---|---|---|---|---|---|
| | Enrolment and allocation | Post-allocation | | | Close-out |
| TIMEPOINT** | 0 | $t_1$ | $t_2$ | $t_3$ | $t_x$ |
| ENROLMENT: | | | | | |
| Eligibility screen | X | | | | |
| Informed consent | X | | | | |
| *Allocation* | x | | | | |
| INTERVENTIONS: | | | | | |
| *KCF manouvre arm* | | | | | x |
| *Standard of care arm* | | | | | x |
| ASSESSMENTS: | | | | | |
| *Baseline characteristics* | X | | | | |
| *Signs of respiratory distress* | | x | X | x | X |
| *Admission, Treatment, mortality* | | X | X | X | X |

** t1 = delivery, t2 = 2 h, t3 = 24 h, tx = discharge.

### 2.11. Allocation of study arms

For allocation to study arms, stratified block randomization will be employed. We will use Recap software for randomization to either the control or intervention arm in a 1:1 ratio. The randomization code will be revealed to the obstetrician or doctor performing the c/s for allocation of the participant to the required arm. It will not be feasible to blind participants and investigators to arm allocation due to the nature of the intervention.

### 2.12. Data collection

After written informed consent is obtained from each participant, baseline characteristics, outcome and other trial data will be entered into the REDCAP database. Source documents include, but are not limited to, hospital records, antenatal cards.

### 2.13. Data management

Data management will be implemented according to Good Clinical Practice (GCP) guidelines. An experienced data manager will maintain the database and check the information in the database for completeness, consistency and plausibility.

The data of all subjects will be coded, and this coding will not be retraceable to the individual patient. The key to this coding is safeguarded by the investigator. A limited number of people have access to the source data. These are the principal investigators and investigating personnel. Personal data are processed only by the researchers or by those who fall directly under their authority. All are subject to the pledge of confidentiality. The data will be stored for 15 years in a strictly confidential manner.

If consent is withdrawn, the coded data collected up to the time of withdrawal will remain part of the study data and will be used for analysis.

### 2.14. Statistical analysis

Statistical analysis will be conducted using STATA version 17. Maternal and child's categorical demographic and clinical characteristics will be summarized using frequency and percentages. Continuous variables such as age, child's birth weight, maternal blood loss during delivery, and APGA score will be summarized using with mean/median and their respective measure of dispersion. To compare the occurrence of respiratory distress between intervention (KCF maneuver) and control groups (standard care), chi square test will be used. The continuous variables such as length of hospital stay, length of neonatal unit admission will be compared using *t*-test. Further logistic regression analysis will be conducted to determine the odds of respiratory distress among control group compared to intervention group, while taking into account other maternal and child's characteristics such as child's presentation during delivery and maternal complications during pregnancy and delivery. Statistical significance is set at $p < 0.05$.

To examine the effectiveness of KCF maneuver in real world setting, intention to treat analysis will be conducted, where by every participant will be analyzed based on their randomization status regardless of whether they comply with the protocol or not.

While the per protocol analysis will also be performed to examine the efficacy of KCF maneuver in an ideal situation, including only participants fully adhered to the intervention comparing to their counterparts.

### 2.15. Oversight and monitoring

A trial management group (TMG) will be appointed and will be responsible for overseeing the progress of the trial. This is a minimal risk study, and no external Data Safety Monitoring Board (DSMB) will be installed. The study will be monitored by an experienced monitor throughout its duration by means of personal visits to the investigator's facilities and through other communications (e.g., telephone calls, written correspondence). Monitoring visits will be scheduled at mutually agreed upon times periodically throughout the study and at a frequency deemed appropriate for the study.

These visits will be conducted to evaluate the progress of the study, ensure that the rights and wellbeing of the subjects are protected, ensure that the reported clinical study data are accurate, complete and verifiable from source documents, and ensure that the conduct of the study is in compliance with the approved protocol and amendments, GCP and applicable national regulatory requirements. A monitoring visit will include a review of the essential clinical study documents (regulatory documents, CRFs, source documents, subject informed consent forms, etc.) as well as discussion on the conduct of the study with the Investigator and staff. The investigator and staff should be available during these visits to facilitate the review of the clinical study records and resolve/document any discrepancies found during the visit.

### 2.16. Reporting of adverse events

#### 2.16.1. Temporary halt for reasons of subject safety

In accordance with section 10, subsection 4, of the Medical Research Involving Human Subjects Act (WMO), the investigator will inform the parents of the subjects and the reviewing accredited Medical Research Ethics Committees, i.e., the Tanzania National Institute for Medical Research (NIMR) and Kilimanjaro Christian Medical College Research Ethics and Review Committee (CRERC), if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by NIMR and CRERC. The investigator will take care that all parents of the subjects are adequately informed.

#### 2.16.2. Adverse events (AEs)

Adverse events (AEs) are defined as any undesirable experience occurring to a subject during the study, whether or not the adverse event was related to the KCF. All adverse events observed by the investigator or his staff will be recorded and noted to the NIMR and CRERC.

#### 2.16.3. Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that; results in death, life threatening (at the time of the event), requires hospitalization or prolongation of existing inpatient hospitalization, results in persistent or significant disability or incapacity, any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgment by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The investigator will report all SAEs to sponsor according to the requirements. The sponsor will report the SAEs to the NIMR and CRERC within 7 days of first knowledge of SAEs that result in death or are life threatening and directly related to the KCF, followed by a maximum period of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of a maximum of 15 days after the sponsor has first knowledge of the serious adverse events.

### 2.17. Protocol amendments and deviations

Protocol amendments will first be sent to the trial sponsors for permission. Thereafter, we will seek ethical approval from the reviewing accredited Medical Research Ethics Committees, i.e., the Tanzania National Institute for Medical Research (NIMR). Only after approval by NIMR will the amended protocol be implemented. All protocol violations and deviations will be reported and resolved according to standard operating procedures (SOPs) that will be developed and also according to funder and ethics board regulations.

### *2.18. Ethics and dissemination*

This protocol has been approved by the Tanzania National Health Research Committee with reference number NIMR/HQ/R.8a/Vol.IX/4331. Furthermore, the Ministries of Health and Regional Administrative & Local Government Authority have endorsed implementation of this protocol.

The results of this trial will be disseminated at relevant local and international conferences as well as within the participating institutions clinical conferences. Additionally, the results will be submitted for publication in open-access medical journals and be shared with relevant local and international stakeholders.

## 3. Discussion

This trial focuses on transition from intra-uterine life to extra-uterine life with respect to the clearance of liquid from fetal lungs at the time of birth so that they can function as an organ of gas exchange. The rationale for a KCF maneuver is based on the fact that, there is strong physiological evidence that respiratory distress (TTN) is caused by the greater volume of airway fluid present at birth resulting in pulmonary oedema and poorer lung function in the immediate newborn period. [13] Therefore KCF has the potential to reduce respiratory distress-related morbidity and mortality in newborn infants born after elective cesarean section.

This clinical trial will test the effectiveness of KCF, as an intervention for reducing respiratory distress in infants born by elective CS. Considering the increasing prevalence of CS worldwide [4], this simple method for reducing excess airway liquid in infants born after elective CS before it is reabsorbed into lung tissue, could potentially decrease the burden of respiratory problems in these infants.

If the outcomes of this trial indicate a positive benefit for KCF, this simple, cost-effective intervention may have the capacity to significantly reduce the respiratory distress affecting infants born by elective CS. Due to the fact that management of respiratory distress can be challenging in low-resource areas such as the sub-Saharan region because of limited access to advanced neonatal care facilities, this intervention will be more beneficial in such settings.

The KCF maneuver could transform standard care around elective cesarean section and lead to considerable improvements in global neonatal health.

## CRediT authorship contribution statement

**Febronia L. Shirima:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation. **Annemarie Keus:** Writing – review & editing, Project administration, Methodology. **Bariki Mchome:** Writing – review & editing, Supervision, Project administration, Investigation. **Glory Mangi:** Writing – review & editing, Investigation. **Indya Davies:** Writing – review & editing, Conceptualization. **Thomas van den Akker:** Writing – review & editing, Supervision, Conceptualization. **Blandina T. Mmbaga:** Writing – review & editing, Supervision, Resources, Project administration. **Stuart B. Hooper:** Writing – review & editing, Conceptualization. **Arjan B. te Pas:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization.

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## Declaration of competing interest

The authors declare that they have no competing interests.

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## Data availability

No data was used for the research described in the article.

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