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Impact of immediate and continuous heart rate feedback by dry electrode ECG on time to initiation of ventilation after birth: protocol for a randomised controlled trial

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ABSTRACT

Introduction 3%–8% of newborns need positive pressure ventilation (PPV) after birth. Heart rate (HR) is considered the most sensitive indicator of the newborns' condition and response to resuscitative interventions. According to guidelines, HR should be assessed and PPV initiated within 60 s after birth in non-breathing newborns. Dry electrode ECG can provide accurate feedback on HR immediately after birth and continuously during resuscitation. The impact of early and continuous HR feedback is unknown.

Method and analysis This single-centre randomised controlled trial seeks to determine if HR feedback by dry electrode ECG immediately after birth and continuously during newborn resuscitation results in more timely initiation of PPV, improved ventilation and short-term outcomes compared with standard HR assessment.

In all newborns≥34 gestational weeks, the dry electrode ECG sensor is placed on the upper abdomen immediately after birth as an additional modality of HR assessment. The device records and stores HR signals. In intervention subjects, the HR display is visible to guide decision-making and further management, in control subjects the display is masked. Standard HR assessment is by stethoscope, gel-electrode ECG and/or pulse oximetry (PO).

Time of birth is registered in the Liveborn app. Time of initiation and duration of PPV is calculated from video recordings. Ventilation parameters are retrieved from the ventilation monitor, oxygen saturation and HR from the PO and gel-electrode ECG monitors.

The primary endpoint is proportion of resuscitated newborns who receive PPV within 60 s after birth. To detect a 50% increase with power of 90% using an overall significance level of 0.05 and 1 interim analysis, 169 newborns are needed in each group.

Ethics and dissemination Approval by the Norwegian National Research Ethics Committee West (2018/338). Parental consent is sought at routine screening early in pregnancy. The results will be published in peer-reviewed journal and presented at conferences.

Trial registration number NCT03849781.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The randomised controlled design and recruitment of study participants early in pregnancy limits the risk of selection bias.
⇒ The multiple data sources needed for assessing the outcomes represents a risk.
⇒ The single-centre design and low proportion of newborns receiving positive pressure ventilation implies a long trial period to reach sample size and represents a risk.

INTRODUCTION

Background

Approximately 85% of newborns born at term initiate breathing within 30 s of birth at median 5 s,[1] and a further 10% will respond to stimulation and drying.[2] Nevertheless, 3–8% of infants require positive pressure ventilation (PPV) after birth.[1 3–6] Delay in initiating, or pauses in PPV, may impair recovery. The risk of death or morbidity in non-breathing newborns increased by 16% per 30 s delay in initiating PPV in a study from a low-resource setting.[1]

Current newborn resuscitation algorithms recommend that PPV should be initiated within 60 s after birth if the newborn fails to establish spontaneous and effective breathing following drying and stimulation, and/or if heart rate (HR) is <100 beats per minute (bpm), HR does not increase if initially low, or HR decreases if initially fast.[4] This is challenging both in low- and high-resource settings.[5 7] In a Norwegian university hospital, assessment of HR and initiation of PPV was only achieved within 60 s in 35% of cases. Median (IQR) time to initial HR assessment

(by stethoscope or palpation) was 70 s (47–118) and preceded initiation of PPV at 78 s (42–118), despite the newborns being placed at the resuscitaire 48 s (22–68) after birth.[7] Assessment of HR may delay starting PPV, and existing technology of standard three-lead ECG and pulse oximetry (PO) has made it difficult to obtain accurate and continuous HR measurements during the first minutes of life when important decisions are made on whether to initiate resuscitation or not.[3]

NeoBeat newborn HR metre (Laerdal Global Health, Stavanger, Norway) was developed for immediate and continuous feedback on HR to guide newborn resuscitation. NeoBeat is a reusable, wireless, low-cost dry electrode ECG device that can rapidly be applied around the newborn's thorax or upper abdomen without prior drying of the skin. Time to place the device is 3 s,[8 9] and a reliable HR is digitally displayed within 5 s after birth in healthy newborns.[9 10] During resuscitation, time from device placement to HR acquisition is faster with NeoBeat (13 s) versus ECG (42 s, p≤0.0001) and PO (105 s, p<0.0001).[8] HR obtained by NeoBeat furthermore correlates well with that of conventional three-lead gel-electrode ECG.[11 12] In a recent cohort of 48 predominantly term newborns who received resuscitation with PPV, the proportion of time with HR feedback from NeoBeat during resuscitation was median 85% from birth and 98% from arrival at the resuscitation table, compared with 25% and 28% with standard ECG. In only 1 of the 48 cases, standard ECG displayed HR before initiation of PPV, as opposed to 38/48 cases with NeoBeat. In 40/48 of cases, NeoBeat was applied and displayed HR within 60 s of birth.[12] Thus, for the first time, an accurate HR can be presented to the healthcare provider (HCP) to guide decision-making immediately after birth and throughout resuscitation, without delaying PPV by HR assessment by auscultation or application of gel-electrode ECG or PO.

A rise in HR is considered the most sensitive indicator of an improvement in the clinical condition of the newborn and effective ventilation during newborn resuscitation.[13] A study from Tanzania showed that for every bpm increase in first detected HR after birth, the risk of death was reduced by 2%. Furthermore, an initial rapid increase in HR to >100 bpm in response to ventilation reduced the risk of death by 75%, whereas a decrease in HR to <100 bpm when PPV was paused was associated with an almost twofold increased risk of death.[14] Hence, newborn HR provide essential information to guide clinical management.

Rationale for the trial and hypothesis

The International Liaison Committee on Resuscitation publishes Consensus on Science and Treatment Recommendations for various topics with a summary of associated knowledge gaps.[3 15] No studies have previously evaluated if immediate and accurate feedback on HR from birth and during newborn resuscitation improves time to life-saving interventions and short-term newborn outcomes.[3 16]

The hypothesis is that immediate and continuous feedback on HR in the delivery room will guide HCPs of the urgency to transfer the newborn to the resuscitaire if the HR is <100 bpm, HR does not increase if initially low, or HR decreases if initially fast. Second, since NeoBeat provide continous HR feedback, initiation of PPV will not be delayed after the newborn is placed on the resuscitaire due to auscultation, application of standard ECG or PO.

In this trial, we will explore if implementation of HR measurement by dry electrode ECG technology increase the proportion of non-breathing newborns who receive PPV within the recommended 60 s after birth by 50% from 35% to 52.5%, compared with conventional monitoring, changes resuscitation interventions and short-term outcomes.

METHODS AND ANALYSIS

Trial design and objectives

This is a single-centre, two-armed, parallel randomised controlled trial in newborns≥34 gestational weeks receiving PPV within 5 min of birth. The trial evaluates the impact of immediate and continuous feedback on HR after birth and during newborn resuscitation by dry electrode ECG technology, NeoBeat, compared with standard monitoring which include auscultation by stethoscope, three-lead gel-electrode ECG and/or PO. The primary endpoint is the proportion of non-breathing newborns where PPV is initiated within 60 s of birth in accordance with resuscitation guidelines. The intervention could not be blinded to the trial participants, HCPs or outcome assessors.

Setting

The trial is conducted at Stavanger University Hospital, Norway. The hospital provides tertiary-level obstetric and neonatal services for 4300 annual deliveries and treats newborns from gestational age (GA) 23 weeks. The hospital is the only hospital in the region and well suited for population-based studies. Delayed cord clamping is practised for healthy newborns. If the newborn require resuscitation, the cord is clamped and cut, and the newborn brought to the resuscitaire located in separate resuscitation rooms on the labour ward. The distance from the delivery rooms to the resuscitation room varies between 3 and 20 m (mean 12 m). For caesarean sections, the resuscitation room is adjacent to the operation theatre. Newborn resuscitation follows national resuscitation guidelines adapted from American Heart Association and European Resuscitation Council guidelines.[4 13] HCPs potentially involved in newborn resuscitations undergo yearly off-site neonatal resuscitation training and fortnightly in situ multidisciplinary team simulation training for those on call. Overall rate of PPV provision at birth is 3.6%, and for newborns with GA≥34 weeks, 2.8%.[6] PPV is primarily performed using the flow-dependent T-piece resuscitator NeoPuff (Fisher&Paykel Healthcare, Auckland, New Zealand) or more infrequently using a

self-inflating bag (Upright, Laerdal Medial, Stavanger, Norway). A midwife, midwife assistant and paediatric resident initiate resuscitation, with the addition of a neonatologist, neonatal nurse, and anaesthesiologist and nurse anaesthetists for complicated resuscitations. In newborns receiving PPV after birth, HCPs are recommended to assess HR by stethoscope, three-lead gel-electrode ECG and PO as soon as time permits. The sequential order of device application is left to the discretion of the attending HCPs.

Eligibility criteria of participants

All in-born, non-breathing newborns receiving PPV within 5 min of birth, with GA≥34 weeks regardless of their birth weight, are eligible for inclusion in this trial.

Newborns are not eligible if born with congenital malformations (omphalocele, gastroschisis) that interfere with the placement of NeoBeat.

Intervention and comparator

All participating newborns have NeoBeat HR metre placed immediately after birth. Newborns randomly assigned to the intervention group have HR visible in the NeoBeat display to guide decision-making and further management of the newborn. Neonates randomly assigned to the comparison group have the NeoBeat display masked by tape, storing HR signal-data but not disclosing the HR to the HCPs.

Primary, secondary and safety outcomes

Primary, secondary and safety outcomes are presented in box 1.

Box 1 Outcome measures

Primary outcome

Proportion of non-breathing newborns who receive PPV within 60 s after birth.

Secondary outcomes

Time in seconds from birth to initiation of PPV.
Duration of PPV in delivery room from first to last inflation (in seconds).
Time from birth to HR≥60, ≥100 and ≥120 bpm as measured by ECG (in seconds).
Time in seconds from birth to oxygen saturation≥95%.
Median tidal volumes and proportion of inflations with tidal volumes≥4, ≥6, ≥8 mL/kg.
Ventilation fraction in the first 30 and 60 s of providing PPV defined as cumulative number of seconds with PPV efforts, including pauses<3 s.
Proportion of newborns with Apgar Score<7 at 5 and 10 min.
Neonatal intensive care unit admission rate among those receiving PPV.

Safety outcomes

Proportion of eligible live births who receive PPV in the two groups.
PPV delivered to newborns after birth despite spontaneous breathing or not delivered to newborns not spontaneously breathing, due to increased focus on resuscitative interventions, as determined by video recordings.
Damage to skin or organs by HR sensor devices.

bpm, beats per minute; HR, heart rate; PPV, positive pressure ventilation.

Sample size calculation and interim analysis

The sample size calculation was based on time from birth to initiation of PPV in a previous study from Stavanger University Hospital in 2016–2017. Among newborns with GA≥34 weeks recieving ventilation within 5 min of birth, 35% received PPV within the recommended first 60 s.[6] To have a power of 90% to detect an improvement to 52.5% receiving PPV within 60 s of birth, we will include at least 169 in each group. Thus, the total sample size will be at least 338 newborns receiving PPV. This sample size calculation is based on using an overall significance level of 0.05 and performing one interim analysis according to the O'Brien and Fleming's procedure.[17] The interim analysis will be done midway. Two stopping rules defined below will be used, one in case of a significant result and one in case of futility. The interim test for significant result will use a significance level of 0.0051. If the trial continues, a significance level of 0.0475 will be used in the final analysis, keeping the overall significance level at 0.05.[17] The trial will be stopped due to futility in case a conditional power analysis shows a conditional power of 0.1 or less, assuming that the original treatment effect is correct.[18 19] The interim analysis will be performed by an independent data safety monitoring board. Adverse events will be reported to the data safety monitoring board.

Randomisation

A computer-generated block randomisation list with variable block size was prepared from randomizer.org March 2019. Randomisation is performed so that newborns born in a particular week receive the same monitoring (NeoBeat display visible in intervention weeks or masked with tape in comparison weeks), as individual randomisation is practically challenging. Randomisation is performed by the research assistant on the first day of the week. We do not think this will introduce bias, as most births occur spontaneously and unplanned.

Implementation of the trial

This clinical trial is conducted in accordance with the clinical trial protocol, good clinical practice and the applicable regulatory requirements. The trial is implemented in a standardised manner. Monthly conferences are conducted to track progress.

Screening and enrolment

Expectant parents are informed about the trial and invited to participate by the midwives at the routine diagnostic ultrasound screening. As parental consents are primarily obtained at routine ultrasound screening in early pregnancy, the risk of selection bias is reduced. For those who have not been asked during early screening, consent is to be obtained on admission to the labour ward. The HCPs will then determine if the mother is physically, psychologically and emotionally fit to provide consent.

Implementation of the intervention

Throughout the trial period, NeoBeat is placed on all participating newborns by the midwife or midwife assistant

immediately after birth as an additional modality for HR detection. Placement of NeoBeat does not interfere with standard care of drying the newborn thoroughly on the mother's abdomen. For caesarean sections, NeoBeat is placed when the newborn is clear of the sterile operation field or on the resuscitation table. For the intervention group, the HR is visible in the NeoBeat display. For the comparison group, the NeoBeat display is masked with tape. NeoBeat is kept on the newborn the initial 5 min after birth or until the newborn is considered respiratory and circulatory stable. If the newborn fails to respond to stabilisation and requires resuscitation, the cord is clamped and cut, and the newborn is brought to the resuscitaire without delay and with the wireless NeoBeat in place. In newborns receiving chest compressions, NeoBeat is, if needed, repositioned to the abdomen of the newborn. HCPs have been trained in standard procedures for applying the NeoBeat and use of the Liveborn app. HCPs are informed that insufficient breathing or HR<100 bpm are indications for starting PPV within 60 s of birth, in line with resuscitation guidelines.

Data collection and definitions

HR signal data from NeoBeat, gel-electrode ECG and PO

The HR from NeoBeat is streamed to and recorded in the Liveborn app, or retrospectively downloaded to the NeoBeat app. HR from ECG and PO will be displayed on the monitor screen (GE Healthcare, Boston, Massachusetts, USA) with video recording for subsequent HR extraction.

Ventilation signal data from the resuscitation monitor

Laerdal Newborn Resuscitation Monitor (Laerdal Global Health) records and stores biomedical ventilation signal data such as applied peak inflation pressures (PIP), positive end-expiratory pressures (PEEP), tidal volumes, mask leak and ventilation rates. The respiration monitor is equipped with a hot-wire anemometer flow sensor (MIM Gmbh, Krugzell, Germany) and a piezo resistive pressure sensor (Freescale Semiconductor, Austin, Texas, USA) connected between the T-piece or bag and the facemask. The resuscitation monitor has a lever formed to hold the T-piece and mask and lifting the T-piece initiates recording. For each inflation, the resuscitation monitor measures and records PIP and PEEP (in mbar, 1 mbar equals 1.02 cmH_20), tidal volume (defined as expiratory volume in ml), leak (defined as difference between inflated and expiratory volume divided by inflated volume, presented as percentage), dynamic lung compliance (mL/mbar), inflation time and instant inflation rate (60 divided by the time interval between current and previous inflation). No visual feedback on ventilation parameters will be displayed to the HCPs. Recorded ventilation data from PPV episodes are downloaded and stored on the research server.

Ventilation fraction is defined as cumulative number of seconds with PPV efforts including pauses<3 s in the first 30 and 60 s of providing PPV, and is calculated from the signal data from the respiration monitor and validated by video recordings. The median tidal volume and proportion of time with tidal volume≥4, ≥6, and ≥8 mL/kg will be calculated from the resuscitation monitor data.

Video recordings of resuscitations

Resuscitations are video recorded using motion sensor triggered optic cameras placed above the resuscitation tables, capturing the newborn and the hands of the HCPs. The timestamps in the video server and Liveborn app are automatically synchronised. Signal data from PPV episodes are stored on the research server. Video recordings are reviewed and data entered by two investigators (SR, AK) to promote data quality, using XProtect Smart Client software V.2016 (Milestone, Copenhagen, Denmark). Video recordings of newborn resuscitations are used to record the time when the newborn is placed on the resuscitation table, placement of the facemask and time for initiation and discontinuation of PPV. Video recordings are also used to validate the respiratory effort of the newborn (spontaneously breathing, gasping or non-breathing), analyse pauses in PPV due to airway suctioning (duration and number of attempts), repositioning of the newborn's head to ensure an open airway, intubation (duration and number of attempts) as well as chest compressions (compressions performed or not and duration).

Patient record information

Information from patient records on maternal risk factors, delivery mode (vaginal, vaginal instrumental, elective or emergency caesarian section), presentation, time of birth, Apgar Score, birth weight, GA, growth restriction, umbilical arterial and venous pH, pCO_2, base excess, newborn malformations, resuscitative interventions, admission to the neonatal intensive care unit, newborn outcomes such as delivery room survival, survival to hospital discharge, hypoxic therapeutic hypothermia treatment, seizures, hypoxic ischaemic encephalopathy, hypoglycaemia (≤1.4 mmol/L) and admission temperature are electronically collected and stored in the research database.

Data storage

All data are collected and stored according to Norwegian and EU regulations.

Data analysis

All analyses will be performed according to intention-to-treat protocol. Even if NeoBeat is not applied, the newborn will not be excluded. Results will be reported by using Consolidated Standards of Reporting Trials statement.

Effect sizes and their 95% CIs will be calculated for the primary and secondary outcomes. Two-sided significance tests at the 0.05 significance level will be performed. For the primary outcome, significance level of 0.0051 will be used at the interim analysis and 0.0475 at the final analysis, giving an overall level of 0.05. If important differences in baseline characteristics between the intervention and

control groups are identified, multiple logistic regression or Cox proportional hazards models will be used to adjust for potential confounding.

Descriptors for background characteristics in the intervention and control groups will be presented in a baseline table and summarised as means/SD or medians/IQRs for continuous variables, according to their distribution, and as frequencies and percentages for categorical variables. These data will represent mode of delivery, sex, birth weight, GA, umbilical arterial pH and Apgar Score.

Flow of participants

The number of participants through assessment of eligibility, consent, randomisation and analysis will be documented. Reasons for exclusions and withdrawals will be described.

A table showing baseline demographic and clinical characteristics for each group will be presented.

Patient and public involvement

A user group were involved in the design and conduct of the trial.

Ethics, dissemination and statements

Inclusion is based on GA≥34 weeks for three main reasons: (1) NeoBeat was only available for newborns with birth weight>1500 g when the trial commenced. (2) The majority of newborns resuscitated due to birth asphyxia are born near term, at term or post term. (3) Newborns with GA<34 weeks are more likely to require ventilation support due to respiratory distress syndrome, and are in our hospital mostly stabilised in open incubators that are not equipped with video cameras for this trial.

The results will be published in a peer-review medical journal and shared with stakeholders through conferences.

Trial status

The trial is ongoing. The first participant was recruited June 2019. Participant recruitment was initially expected to be completed by June 2022. The current protocol is V.5.0, dated 1 October 2021.

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Contributors SR is the principal investigator; she conceived the study, led the proposal and protocol development. HLE, KS, KH, HMP, JH and PGD contributed to the study design and to development of the proposal. SR and HLE were the lead trial methodologists. SR, PAB, JH are grant holders. JTK provided statistical expertise in clinical trial design and is conducting the primary statistical analysis. JE contribute to data analysis and interpretation of the data. AK, PAB, JH, HMP, SR and TBT participated in the data collection. All authors were involved in writing the manuscript and approved the final version.

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Competing interests JE is a Laerdal Medical employee. PAB and JH have an unconditional PhD grant from the Laerdal Foundation (PB Bjørn Lind Grant no 30 026 and JH Safer Healthcare grant no 5007). SR has an unconditional research grant from the Laerdal Foundation (Safer Healthcare grant no 5007). The other authors declare no conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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