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Monitoring during newborn kangaroo care

Submission date
13/09/2024

Recruitment status
No longer recruiting

Registration date
10/12/2024

Overall study status
Completed

Last Edited
10/12/2024

Condition category
Neonatal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Kangaroo care or skin-to-skin is part of a package of measures called family-integrated care that allows parents to be more involved in the care of their infant. Studies show kangaroo care is associated with significant benefits from reducing death rates, hospital-acquired infections, shorter hospital stays, improved temperature regulation and better neonatal parent psychological well-being.
Despite the considerable positive evidence the uptake of kangaroo care is relatively limited in the UK. Barriers identified by healthcare professionals to delivering regular, quality kangaroo care are workload, lack of time, resources and suitable monitoring equipment. A new wireless, strap-based vital sign device has been developed which can be placed on the infant's body during kangaroo care. The KangaCare monitoring system is capable of measuring oxygen levels, heart rate and skin temperature, potentially addressing the shortcomings of current monitoring systems.
This study aims to compare the accuracy of the new wireless KangaCare monitoring system in measuring oxygen levels, heart rate, pulse rate and temperature, against current monitoring devices used in practice during kangaroo care.

Who can participate?
1. Infants requiring vital sign monitoring who are deemed clinically stable enough to receive KC by the usual clinical care team
2. Parents/carers over the age of 16 years
3. Healthcare providers

What does the study involve?
Infants will wear the new KangaCare Monitoring system to record vital sign signals for heart rate, oxygen levels and temperature alongside currently used ECG, pulse oximetry and temperature measurement devices for comparison. Parent/carers wear visual attention glasses and smartwatches during kangaroo care to measure their gaze and heart rate.

What are the possible benefits and risks of participating?
There are no immediate benefits to the participants, but data from this study will help further the development of the device and improve the delivery of kangaroo care for infants in the

future. The device has undergone rigorous safety testing and we do not envisage any significant risks associated with the device. Participants will be informed of a potential risk of skin redness or irritation. Any adverse device effects will be reported via the MHRA MORE portal.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2022 to March 2025

Who is funding the study?
Innovate UK

Who is the main contact?
Prof. Don Sharkey, don.sharkey@nottingham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333116

Protocol serial number
CPMS 62155, IRAS 333116, Innovate UK Grant Code: 10037266

Study information

Scientific Title
KangaCare - wireless monitoring during Kangaroo Care

Acronym
KangaCare

Study objectives
The use of a new wireless monitor for newborn kangaroo care in the neonatal unit provides vital sign measures similar to current devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2024, North Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 24/NS/0043

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal health

Interventions
There are three recruitment arms for the study to address the primary and secondary outcomes outlined. All three parts will require participants to give informed consent, and researchers will follow the Good Clinical Practice (GCP) regulations in obtaining this.

1. KangaCare monitoring system study (KC-MS)
The infant participant is identified by the clinical care team as stable for kangaroo care and that the infant meets inclusion and exclusion criteria. The parent is approached with a study information leaflet and then to gain informed consent.
The KC-MS will be attached to the infant following which measurements of heart rate, pulse rate, oxygen saturation and temperature will be taken. The research team, with the clinical team, will help attach the KC-MS device prior to starting kangaroo care. The infant will continue to be monitored by the usual clinical monitors (predicate devices) in the form of ECG, pulse oximeter and temperature, no data from the KC-MS will be shared with the clinical team or be used for clinical care as this is to be analysed off-line later.

Raw signals from the optical, electrical and temperature sensors on the KC-MS will be obtained during the study as well as conventional heart rate, pulse rate, oxygen saturation and temperature monitoring will remain in place for comparison, and data will be obtained from these devices using a laptop connected to monitoring docking device for data collection. The clinical staff or a member of the research team will also take additional temperature readings approximately every 15 minutes during the study period, using a standard neonatal

thermometer already used in clinical practice if continuous temperature monitoring is not used. Other data collected will include any interventions made by clinical staff at the time of the recording such as nasogastric feeding, medicine administration, and adjustment to any of the monitoring or positioning of the infant. The recording will end when the infant is returned to the incubator at the end of their kangaroo care. Each infant recruit can have up to 6 episodes of kangaroo care with the KC-MS device. These subsequent episodes will occur on separate days and be guided by the infant's usual care clinical team. One episode of kangaroo care can last between 15 to 90 minutes.

Clinical data taken from the infant and maternal medical notes (only if the mother is providing consent so not if a father/carer is consenting) will include:
• Demographics including gestation, age at entry, birth weight, current weight, birth order (if applicable), Fitzpatrick skin type, antenatal scans, APGARs, maternal and infant medical problems and treatments
• Data to confirm eligibility
• Any observations made during the data collection period immediately before, during and after the kangaroo care episode.
The research team will be responsible for the devices and will follow the manufacturer's instructions in terms of use and storage.

2. Parent/carer and healthcare professional feedback
Following the use of the KC-MS, 10 parents/carers and 10 healthcare providers will be recruited to undertake a brief feedback session to capture their insights into the new device. This will be a 10–15-minute semi-structured questionnaire to capture both specific (closed questioning) and more open responses. This will be given to participants in a paper form.

3. Visual attention study
Parents/carers consenting to participate in the visual attention study during kangaroo care will be positioned as normal by the attending clinical team and a 'smart' watch capable of monitoring heart rate and other vital signs will be placed on their wrist to collect these data. When the parent and clinical team are happy, the parent study will begin. The parent will wear a set of glasses which house a visual attention system to track what they are looking at, no sound will be recorded. The clinical team will then move the baby for kangaroo care to which the recording will commence. The recording will end when the infant is returned to their incubator and completes kangaroo care. This will also highlight the end of parent/carer participation in the study. The visual attention glasses use video recording to allow gaze quantification. As this part of the study involved a video recording in a clinical area, measures will be put in place to minimise the number of people captured in any videos. Prior to starting the study, a privacy screen will be placed around the participating infants' cot space to minimise the capture of others in the area. A large sign will be placed on the entrance to the clinical space that informs all in the area that a research study is in progress that includes capture of video within that area. All staff and parents/carers in the bay will have access to a short information leaflet detailing the study. A researcher will wait at the entrance of the participant cot space to ensure anyone wishing to enter is aware of the use of video capture for research and that they recognise they will be recorded and verbally consent to this. Video from the study will be kept secure and only be viewed by the named research team. Where data/images are presented or published, all identifiable information will be removed, for example faces blurred out. There is the potential to have many staff and visitors, some of whom this will be their first and last visit, entering the clinical space during video recording. It is there impractical to seek written consent from such a large group beyond notification at the entrance to the clinical space. 25 parents/carers will recruited as part of the visual attention study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
KangaCare monitoring system (KC-MS)

Primary outcome(s)
The accuracy and reliability of the KangaCare Monitoring System at measuring heart rate (bpm), oxygen saturation (%) and temperature (oC) compared with predicate pulse oximetry, ECG and temperature measurement devices currently used in practice. This will be measured by obtaining measurements of heart rate, oxygen saturation and temperature using the KangaCare monitoring system device alongside measurements of heart rate using ECG, oxygen saturation and temperature from monitoring devices currently used in neonatal clinical practice, recorded during each episode of routine Kangaroo care.

Key secondary outcome(s))
1. Parent and staff feedback on the wireless device, collected using a paper-based questionnaire after using the KangaCare Monitoring system over the study recruitment period.
2. Visual attention of parent/carer during kangaroo care based on percentage time looking at their infant, clinical space and other people in their clinical area. This will be collected using visual attention glasses during an episode of routine Kangaroo care.

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Infants who are deemed clinically stable enough to receive kangaroo care by the usual clinical care team
2. Infants requiring vital sign monitoring
3. All infants must have written informed consent from the parent

Feedback and visual attention study:
Parents/carers over 16 years old and healthcare providers who can provide informed written consent are eligible for the study.

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Mixed

Sex

All

Key exclusion criteria
1. Infants who are undergoing end-of-life comfort care
2. Infants undergoing body cooling as part of their treatment
3. Infants who are deemed by clinical staff to be too unstable for kangaroo care

Date of first enrolment
03/09/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham Neonatal Service
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Don Sharkey (don.sharkey@nottingham.ac.uk). The data will become available through published work and shared with participants whose consent has been ascertained. All data included in publications will be anonymised and will meet ethical and legal restrictions as outlined in the study protocol.

IPD sharing plan summary
Available on request