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Developing a new vital sign monitor for newborn babies

Submission date
16/12/2024

Recruitment status
No longer recruiting

Registration date
14/04/2025

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Approximately 10% of newborns require help with adapting to life outside the womb at birth. Providing this assistance using international guidelines based on the latest medical evidence has been shown to improve survival and reduce disability. Delivering the best possible care in the first 5 to 10 minutes of life requires a complex approach involving rapid, accurate and reliable monitoring of heart rate, blood oxygen levels and temperature. Applying each piece of monitoring equipment separately and waiting for the devices to provide an accurate reading takes time, delaying crucial information. This equipment is also typically wired and thus can cause physical disruption during the process of monitoring.

This research study will test a new wireless monitoring device (VS Patch) which can measure heart rate, blood oxygen levels and temperature in newborn babies at delivery. All of the sensors which are required for these measurements are present on this single device which can be placed directly on to the babies' chest. Information from the device is sent wirelessly to a monitor through an electronic module, avoiding cables trailing from the baby to the monitor.

Who can participate?
Newborn babies on the labour ward and neonatal unit above 24 weeks gestation can participate in the study.

What does the study involve?
The VS Patch device will be attached to babies alongside currently used monitoring devices, leaving these in place for up to one hour. Once the monitoring is complete, all of the trial equipment will be removed from the baby.

What are the possible benefits and risks of participating?
There is no intended benefit for participating babies, but we hope babies born in the future will benefit from this research by helping help doctors, nurses and midwives look after newborn babies better.

The device shines a light on to the babies’ skin to measure their blood oxygen levels and heart rate. It is possible that heat from the light could cause redness to babies’ skin. This is very

unlikely to happen because the light source will not come into contact with the skin, its use will be for a short time and closely monitored. Current oxygen monitoring devices use a similar light with no problems when used like this. If there is any redness the device will be removed. As with all devices for patient care, these have been tested for safety by the hospital engineers. If during any part of the study, the clinical or research team feel that the study is impacting on the care of the baby or mother, then the research team will end the observation and remove the study monitoring equipment.

Where is the study run from?
The study is run from the Centre for Perinatal Research (CePR) within the University of Nottingham (UK).

When is the study starting and how long is it expected to run for?
June 2024 to January 2026

Who is funding the study?
The study is being funded by the National Institute for Health and Care Research in the UK.

Who is the main contact?
Professor Don Sharkey, Chief Investigator, don.sharkey@nottingham.ac.uk
Dr Syed Taha, Clinical Research Fellow, syed.taha@nottingham.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
331800

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 63789, NIHR204171

Study information

Scientific Title
VS Patch: A wireless, multiparameter newborn monitoring system for resuscitation at birth

Study objectives
This research study will test a new wireless monitoring device (VS Patch) which can measure heart rate, blood oxygen levels and temperature in newborn babies at delivery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/08/2024, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 24/NS/0085

Study design
Interventional non-randomised

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Measure heart rate, blood oxygen levels and temperature in newborn babies

Interventions
This is an observational study. We will evaluate the VS Patch device on 50 newborn babies; this number has been selected to satisfy requirements stipulated by regulatory bodies. These babies will be recruited from two labour suites and two neonatal units. We will recruit babies ranging from 24 weeks gestation upwards. We will aim to include at least 15 dark-skinned participants to ensure good representation. Consent will be obtained from all of the babies' parents before entry into the study.

Within the labour suites, 20 babies will be recruited. The obstetric or midwifery teams will inform the research team of any imminent deliveries where consent has been taken. The research team will attend the delivery and attach the VS Patch device to the baby at birth alongside currently used monitoring devices, leaving these in place for one hour if possible. Once the monitoring is complete, all of the trial equipment will be removed from the baby. If required, a neonatal team will be in attendance to provide assistance to the baby. If during any

part of the study, the neonatal, research or obstetric team feel that it is impacting on the care of the participant or the mother, then the research team will end the observation and remove the monitoring equipment.

Within the neonatal units, 30 babies will be recruited. The research team will liaise with the neonatal team to identify babies who are medically stable. The research team will attach the VS Patch device to the baby alongside currently used monitoring devices, leaving these in place for one hour if possible. Once the monitoring is complete, all of the trial equipment will be removed from the baby. If during any part of the study, the neonatal or research team feel that it is impacting on the care of the participant, then the research team will end the observation and remove the monitoring equipment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VS Patch

Primary outcome(s)
Measurement of heart rate and oxygen saturations by the VS patch compared with predicate devices in clinical use (ECG and pulse oximeter) during neonatal care

Key secondary outcome(s))
1. Signal acquisition time (seconds) of VS Patch device for a) ECG and b) photoplysthmogram of optical signal from time of placement on baby
2. Comparison of surface temperature measurement of VS Patch (oC) compared to standard clinical measures taken by attending clinical team during first hour of patch in place

Completion date
30/01/2026

Eligibility

Key inclusion criteria
1. Infants of 24 weeks gestation and above within the labour suite and anticipated to need vital sign monitoring
2. Infants of 24 weeks gestation and above within the neonatal unit deemed stable by the clinical team and undergoing vital sign monitoring
3. All infants must have verbal or written informed consent from the parent/carer
4. All infants must have a realistic prospect of survival as determined by the attending clinical team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Sex
All

Key exclusion criteria
1. Infants that are not for active resuscitation
2. Infants that are receiving therapeutic hypothermia
3. Infants that are undergoing end-of-life care
4. Infants that have had surgery involving the chest/upper abdominal area
5. If multiple births, then only the first baby born shall be recruited (due to resource limitations with equipment and researchers attending the birth)

Date of first enrolment
01/11/2024

Date of final enrolment
30/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
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
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes