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# Supporting future heart screening in newborn babies through testing of two oxygen sensors linked to a mobile app

**Submission date**
13/10/2026

**Recruitment status**
Not yet recruiting

**Registration date**
14/10/2026

**Overall study status**
Ongoing

**Last Edited**
18/11/2026

**Condition category**
Pregnancy and Childbirth

[X] 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
Congenital heart disease (CHD) affects around 6,000 newborn babies in the UK each year. Current national screening includes an ultrasound scan during pregnancy and a newborn examination after birth. Some hospitals also use pulse oximetry as an additional check, but some babies with CHD can still be missed.

Pulse oximeters are small sensors that measure blood oxygen levels and pulse rate. They also produce a pulse-wave signal containing information about the circulation. Comparing signals recorded at the same time from a baby's upper and lower limbs may provide useful additional information. Pulse oximetry may also perform differently across different skin tones.
This study aims to find out whether two pulse oximeters connected to a mobile app can reliably collect good-quality signals from a newborn baby's upper and lower limbs during newborn care. This study will also assess whether the approach is practical and acceptable to parents and NHS staff. The study is not designed to diagnose heart disease or determine whether this approach improves screening.

Who can participate?
Healthy babies born at term, term babies with suspected or confirmed congenital heart disease, and preterm babies with a patent ductus arteriosus (PDA) who are receiving drug treatment as part of their usual clinical care. Parents or other people with parental responsibility may complete a questionnaire, and also be invited for an interview. NHS staff who have used the study system may complete a questionnaire, and be invited for an interview.

What does the study involve?
Two soft pulse-oximeter sensors are placed on the baby, one on the right hand or wrist and one on either foot. Once stable signals are obtained, oxygen saturation, pulse rate, pulse amplitude and pulse-wave signals from both limbs are recorded simultaneously for a target of five minutes using the research mobile app. Skin tone beside each sensor site is also assessed independently

by two trained members of the study team using a six-tone shade card, and relevant information is collected from the medical record. The app is used only to collect research data and does not provide a screening result, diagnosis or treatment recommendation.

Healthy term babies usually have one recording. Babies with suspected or confirmed CHD may have a second recording after 24 hours of age or at routine follow-up at around one month. Preterm babies with PDA have recordings before and after clinically indicated drug treatment. Parents and staff may also be invited to complete short questionnaires and, for a smaller group, an optional interview about their experience of the study.

What are the possible benefits and risks of participating?
There is no expected direct medical benefit to babies or other participants. The information gained may help researchers decide whether this approach should be investigated in a larger future study aimed at improving the early detection of congenital heart disease.

The study procedures are low risk and non-invasive. The sensors are routinely used in newborn care, although their placement may occasionally cause brief discomfort, temporary skin marking or disturbance. Clinical care will always take priority and a recording can be delayed or stopped if the baby becomes unsettled or unwell. Questionnaires and interviews require some additional time, and some parents may find discussing their experiences or their baby's condition upsetting.

Where is the study run from?
The study is sponsored by University Hospitals Sussex NHS Foundation Trust. Initial recruitment and data collection will take place at the Royal Sussex County Hospital, Brighton. Additional University Hospitals Sussex locations may be added later if required and appropriately approved.

When is the study starting and how long is it expected to run for?
The first participant is expected to be enrolled in December 2026, with recruitment and participant data collection planned until April 2028. The overall research project funding runs until June 2028, allowing time for final analysis and reporting.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme, UK.

Who is the main contact?
Dr Ramon Fernandez, Chief Investigator, Brighton and Sussex Medical School, ramon.fernandez@nhs.net

# Contact information

### Type(s)
Principal investigator, Scientific, Public

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# Additional identifiers

### Integrated Research Application System (IRAS)
354683

### Central Portfolio Management System (CPMS)
66862

### National Institute for Health and Care Research (NIHR)
209778

# Study information

### Scientific Title
Improving newborn screening for congenital heart disease using dual pulse oximeter signals and a mobile app: a feasibility study

### Study objectives
Primary objective
To assess the feasibility of simultaneously collecting dual pulse oximetry data from the upper and lower limbs, including $SpO_2$, pulse rate, pulse amplitude index (PAI) and plethysmographic waveform data, during routine newborn checks using Bluetooth transmission to a mobile app.

Secondary objectives
1. To collect normative $SpO_2$, pulse rate, PAI and pleth waveform data from healthy term newborns during the routine newborn check.
2. To develop and apply analytical methods for $SpO_2$ variability, pulse-rate variability, pleth waveform morphology and upper-to-lower-limb time/phase differences in the pleth trace.
3. To collect exploratory dual pulse oximetry data in term newborns with suspected or confirmed congenital heart disease, including one repeat recording after 24 hours of age or at routine clinical follow-up at around one month after birth.
4. To collect exploratory dual pulse oximetry data in preterm newborns with echocardiography-confirmed patent ductus arteriosus before and after clinically indicated pharmacological treatment.
5. To assess the usability and acceptability of the dual pulse oximetry app to parents and clinical staff.
6. To evaluate the operational feasibility of recruitment, data collection, integration into routine clinical workflow, follow-up recording attainment and data processing, in order to inform the design of a future larger study.
7. To record skin tone using a six-tone visual shade card and explore whether dual oximetry and pleth waveform analysis may help address known limitations of conventional pulse oximetry across a range of skin tones.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 29/10/2026, South West - Central Bristol Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8012; centralbristol.rec@hra.nhs.uk), ref: 26/SW/0115

## Primary study design
Interventional

## Allocation
N/A: single arm study

## Masking
Open (masking not used)

## Control
Uncontrolled

## Assignment
Single

## Purpose
Prospective, non-randomised feasibility research-specific study of dual-sensor pulse-oximetry recording using two CE-marked pulse oximeters and a research mobile application

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Congenital malformations of the circulatory system

## Interventions
This is a prospective, non-randomised exploratory feasibility study with four work packages running in parallel. It will assess whether dual pulse-oximetry recordings can be collected reliably in newborn-care settings and whether the approach is practical and acceptable to parents and NHS staff. It is not designed to establish diagnostic accuracy or clinical effectiveness.

Families may receive study information antenatally, following the routine 20-week scan appointment, at a later antenatal appointment or through another approved maternity pathway. Information may also be provided postnatally when appropriate. Consent must be received from a parent or other person aged 16 years or over with parental responsibility before any research procedure or research use of clinical information. Where consent was received antenatally, the baby's eligibility and clinical suitability and the parent's continuing willingness will be confirmed after birth before the first research procedure.

Each participating baby will be assigned a study ID. Relevant demographic and clinical information will be collected from the medical record after consent. Two soft pulse-oximeter sensors will be placed on the right hand or wrist and either foot. Once stable signals are obtained, oxygen saturation, pulse rate, pulse amplitude and pulse-wave data from both limbs

will be recorded simultaneously for a target of five minutes using the mobile app. The app data are for research only and will not provide a screening result, diagnosis, clinical alert or treatment recommendation. The recording may be delayed, stopped or omitted if the baby becomes unsettled or clinically unsuitable or requires care.

Skin tone will be assessed at the time of the pulse-oximetry recording by two trained staff using a six-tone visual shade card. Separate ratings will be made on uncompressed skin adjacent to the upper- and lower-limb probe sites. The assessment is visual only and does not involve photography.

Work Package 1: Up to 80 healthy term babies will have one recording during or around the routine newborn check, typically 4–8 hours after birth. There is no further newborn follow-up.

Work Package 2: Up to 20 term babies with suspected or confirmed congenital heart disease will have one initial recording during the relevant postnatal clinical pathway. Where clinically and practically feasible, they will have one repeat recording after 24 hours of age or at routine clinical follow-up at approximately one month.

Work Package 3: Up to 20 preterm babies with an echocardiography-confirmed patent ductus arteriosus will have two recordings during their neonatal admission: one before and one after clinically indicated drug treatment. The decision to treat, choice of medication and timing of treatment will be determined entirely by the clinical team and will not be influenced by the research.

Work Package 4: After the baby's study procedure, one parent or person with parental responsibility may be invited to complete a questionnaire lasting approximately five minutes. Up to 120 parents may participate. A purposive sample of up to 15 may also be invited to one optional interview, usually approximately 6–8 weeks later. Up to 30 staff who have used the app may complete one usability questionnaire, and up to 10 of them may also participate in one optional interview. Interviews may be conducted in person, by telephone or by secure video call and will usually last 30–45 minutes. Separate information and consent will be provided for questionnaires and interviews, including separate consent for audio recording.
The study will run for 24 months. Clinical care will not be delayed or altered by any study procedure.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Nonin 3150BLE pulse oximeters

## Primary outcome(s)
1. Recording adequacy, defined as the proportion of attempted 5-minute dual-limb pulse oximetry recordings that provide at least 20 continuous seconds of interpretable, simultaneous oxygen saturation ($SpO_2$), pulse rate (PR), pulse amplitude index (PAI) and plethysmographic waveform data from both channels, measured using physiological data recorded by the two Nonin 3150BLE pulse oximeters via the research mobile app at each attempted recording in Work Packages 1–3

### Key secondary outcome(s)
1. Recruitment feasibility and participant diversity measured using screening, enrolment and study records, including the proportion of approached eligible families consenting, monthly recruitment rate by work package, reasons for non-participation where collected, ethnicity, deprivation indicators where collected and observed skin-tone distribution, at recruitment and reviewed monthly

2. Recording completeness and signal quality measured using the dual-channel physiological data files, including duration and completeness of simultaneous $SpO_2$, PR, PAI and pleth waveform data and the proportion of artefact-affected, incomplete or unusable recordings, at each recording in Work Packages 1–3

3. Feasibility of integration into routine care measured using recording/procedure duration, the proportion of recordings completed within the routine clinical workflow and documented adherence to the recording procedure, using study procedure records/CRFs, at each relevant Work Package 1–3 recording

4. Parent/family acceptability and staff usability/acceptability measured using the study-specific parent/family questionnaire, staff usability and acceptability questionnaire and qualitative interviews, at study involvement for completion of questionnaires, approximately 6–8 weeks after the baby's participation for parent/family interviews, and during the study data-collection period for staff interviews

5. Follow-up recording feasibility measured using study records as the proportion of Work Package 2 participants completing the planned repeat recording after 24 hours of age or at routine clinical follow-up at around one month, and the proportion of Work Package 3 participants completing paired recordings at timepoints before and after clinically indicated pharmacological PDA treatment

6. Data-transfer and processing feasibility measured using data-transfer and verification records, including successful transfer and verification of complete physiological files and completion of the signal-analysis pipeline, at following each data transfer and during signal analysis

7. Physiological signal characteristics measured using the dual pulse oximetry recordings, including $SpO_2$, PR, PAI, pleth waveform indices, pre-ductal/post-ductal differences and upper-to-lower-limb phase/time-delay measures at the Work Package 1 routine recording, Work Package 2 initial and repeat recordings, and Work Package 3 pre- and post-treatment recordings

### Completion date
30/04/2028

## Eligibility

### Key inclusion criteria
1. Newborn participants: Newborn babies receiving care through participating UHSx maternity, postnatal, neonatal, paediatric cardiology or follow-up pathways may be eligible if they fall into one of the following groups:
1.1. WP1: Healthy term newborns born at > = 37+0 weeks' gestation who are clinically stable and undergoing or available for the routine newborn check, with recording planned during or around the newborn check, typically 4–8 hours after birth where clinically and practically appropriate.
1.2. WP2: Term newborns born at > = 37+0 weeks' gestation with suspected or confirmed

congenital heart disease, who are clinically stable enough to undergo a brief non-invasive recording and can attend or be accessed at the relevant follow-up site where applicable.
1.3. WP3: Preterm newborns born at < 37+0 weeks' gestation with a patent ductus arteriosus confirmed on routine clinical echocardiography, where the clinical team has independently decided to undertake clinically indicated pharmacological treatment and considers the baby clinically stable enough for brief non-invasive probe placement and recording.
1.4. For all newborn participants, the responsible clinical team must consider dual-sensor pulse oximetry probe placement on the right hand or wrist and either foot clinically appropriate and safe. Written informed consent must be received from a parent or other person aged 16 years or over with parental responsibility before any research-specific procedure or extraction of clinical information for research.
1.5. Each newborn from a multiple pregnancy will be assessed independently against the relevant eligibility criteria, and consent will be received separately for each baby enrolled.

2. Parent/family questionnaire and interview participants:
2.1. One parent or other person with parental responsibility linked to each enrolled newborn may participate in the parent-facing study components. They must be aged 16 years or over, able and willing to provide informed consent for their own participation, and able to complete a questionnaire and/or take part in an interview in English or with approved language support where this is available and sufficient to support valid informed consent and meaningful participation.

3. Staff questionnaire and interview participants:
3.1. NHS staff, including midwives, neonatal nurses or doctors, who have used the dual-sensor app during the study and are willing to complete a questionnaire and/or take part in an interview.

### Healthy volunteers allowed
Yes

### Age group
All

### Lower age limit
0 Days

### Upper age limit
120 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Newborn participants: Newborn babies will not be enrolled where any of the following apply:
1.1. The newborn is acutely unwell, requires urgent clinical intervention, or is judged by the attending clinician to be clinically unstable such that the research procedure would be inappropriate or could interfere with clinical care
1.2. A skin condition, wound, dressing, bandage, splint, intravenous or arterial line, limb

malformation, amputation, congenital abnormality, phototherapy equipment or other clinical equipment prevents simultaneous safe placement of one pulse oximetry sensor on the right hand or wrist and another on at least one foot
1.3. The same newborn has already been enrolled in another newborn work package or has been enrolled previously in the same work package. Planned repeat or paired recordings undertaken within the assigned work package are not considered duplicate enrolment.
1.4. An active safeguarding concern makes research approach inappropriate at that time
1.5. The attending clinician considers research approach or enrolment inappropriate for clinical, welfare or other reasons
1.6. Valid written informed consent has not been received from a parent or other person aged 16 years or over with parental responsibility
1.7. Parent or other person with parental responsibility who requires language support to provide valid informed consent, where sufficient approved language support, such as a professional interpreter and/or approved translated materials, cannot be arranged within the relevant clinical timeframe. Family members or untrained staff will not be used as interpreters for informed consent.
1.8. A parent aged under 16 years will not be asked to provide consent for the newborn's participation
1.9. Where another person aged 16 years or over with parental responsibility is available and able to provide informed consent, the newborn may still be considered for enrolment; otherwise, the newborn will not be enrolled

2. Parent/family questionnaire and interview participants: Parent/family participants will not be enrolled if they:
2.1. Are aged under 16 years
2.2. Are unable or unwilling to provide informed consent for their own participation
2.3. Lack capacity to provide informed consent
2.4. Cannot participate meaningfully in English and sufficient approved language support is unavailable

3. Staff questionnaire and interview participants: Staff will not be enrolled if they:
3.1. Have not used the dual-sensor app during the study
3.2. Are unable or unwilling to provide informed consent
3.3. Lack capacity to provide informed consent

### Date of first enrolment
01/12/2026

### Date of final enrolment
30/04/2028

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre

**Royal Sussex County Hospital**
Eastern Road
Brighton
England
BN2 5BE

# Sponsor information

**Organisation**
University Hospitals Sussex NHS Foundation Trust

**ROR**
https://ror.org/03wvsyq85

# Funder(s)

**Funder type**
Government

**Funder Name**
Research for Patient Benefit Programme

**Alternative Name(s)**
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Data sharing statement to be made available at a later date