ISRCTN10302534 https://doi.org/10.1186/ISRCTN10302534

Application of opaque wrap for improving pulse oximeter sensitivity in neonates: a randomised controlled trial

Submission date 25/03/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/04/2018	**Overall study status** Completed	
Last Edited 23/11/2020	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Oxygen is carried in the blood attached to hemoglobin molecules. Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry. Oxygen saturation can be measured non-invasively using pulse oximetry. The pulse oximeter probe is often covered with an opaque wrap, as environmental or phototherapy light could interfere with the oxygen saturation measurement. The aim of this study is to find out whether covering the pulse oximeter sensor with an opaque wrap will provide a more accurate reading and faster result.

Who can participate?
Infants in the neonatal intensive care unit or postnatal ward of University Hospital of North Tees

What does the study involve?
Infants are randomly allocated to undergo pulse oximeter recording using a sensor either with or without an opaque wrap. They then switch over to the other type of sensor for another recording. This data is not be used for treatment - a separate pulse oximeter is used if needed.

What are the possible benefits and risks of participating?
There won't be any direct benefit to participants, but this study will help to improve the understanding of oxygen saturation measurements in newborns. Since this study doesn't involve any invasive procedures there won't be any discomfort /risk of participating.

Where is the study run from?
University Hospital of North Tees (UK)

When is the study starting and how long is it expected to run for?
January 2018 to March 2019

Who is funding the study?
Local R&D incentive funding

Who is the main contact?
Dr Prakash Loganathan

Contact information

Type(s)
Scientific

Contact name
Dr Prakash Kannan Loganathan

ORCID ID
http://orcid.org/0000-0003-3717-8569

Contact details
University Hospital of North Tees
Hardwick Rd, Hardwick
Stockton-On-Tees
United Kingdom
TS19 8PE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CH-OPUS-Version 16

Study information

Scientific Title
Opaque wrap for PUlse oximeter Sensor in neonates

Acronym
OPUS

Study objectives
Application of opaque wrap to pulse oximeter sensor (OWPS) obtains faster results (saturation, heart rate) when compared to sensor application without any opaque wrap (PS) in ambient light and phototherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design
Interventional single-center randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Neonatal oxygen saturation monitoring

Interventions
There will be two stratum (groups) based on gestation: >27 weeks to 34 weeks; >34 weeks. This will help in having a sufficient number of small babies and validate the data in small babies. Recruitment will start after 24hrs to allow sufficient time for transition, until their hospital stay. Random numbers will be created using online tool by one of the research team member who is not involved in recruitment. The sequence will be generated and stored in an opaque-sealed envelope. This envelope will be opened after parent's consent, at the time of recruitment. Blinding is not feasible due to the nature of the intervention, but all the pulse oximeter recordings will be blinded. Moreover, downloaded data doesn't contain any information regarding the intervention received.

1. Opaque wrap with pulse oximeter sensor (OWPS)
2. Pulse oximeter sensor without any opaque wrap (PS)

Each infant after the initial intervention (OWPS or PS) based on randomization will cross over to the other intervention subsequently for another period of 10 minutes. For example, if an infant is initially randomized to OWPS, the trialists will perform pulse oximeter recording with opaque wrap for a period of 10 minutes, following which the same infant will undergo another 10 minutes of pulse oximeter recording without opaque wrap. The subsequent intervention will be carried out after restarting the pulse oximeter machine and the sensor will be applied on the same foot. The advantage of this method is that the same infant could act as own control, to compare the two techniques in the same infant. Both Nellcor and Masimo recording will be carried out simultaneously in both feet, so each infant will undergo total of 20 minutes of recording.

All the study recordings will happen during the daytime and with hospital/intensive care /ambient light or phototherapy. The data from the research pulse oximeters will not be used for any clinical management; a separate pulse oximeter from the neonatal unit attached to wrist

(right/left) will be used for all the clinical management, if needed. These recordings will be done when the infant is quiet/sleep state. This recording will occur under the direct supervision of one of the investigators. Medical team/parents will be able to carry out routine activities, if needed.

Intervention Type
Device

Primary outcome measure
The time to display a valid data for the two techniques (pulse oximeter sensor with opaque wrap versus pulse oximeter sensor without opaque wrap). Total duration of recording will be for 10 minutes from the time of valid data display. Valid data as per study protocol definition. These data will be downloaded directly from both monitors into research laptop

Secondary outcome measures
1. Number of valid data points for the two techniques (OWPS and PS) during the 10 minute recording will be compared from the downloaded data
2. Number of artifacts for the two techniques (OWPS and PS) during the 10 minute recording will be compared from the downloaded data. Artifacts as per study protocol definition

Overall study start date
01/01/2018

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. All infants ≥27 weeks of gestation
2. Neonates admitted in neonatal intensive care unit or postnatal ward
3. A parent or guardian is able and willing to provide informed consent

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
100

Total final enrolment
117

Key exclusion criteria
1. Antenatal or postnatal diagnosed major congenital malformations (e.g. congenital diaphragmatic hernia, congenital heart disease, hydrops, lung malformation and known blood

dyscrasias)
2. Neonates who are undergoing therapeutic hypothermia, as hypothermia could interfere in pulse oximeter sensitivity
3. Critically ill Infants based on the discretion on medical team

Date of first enrolment
01/06/2018

Date of final enrolment
30/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of North Tees
Hardwick Rd
Hardwick
Stockton on Tees
United Kingdom
TS19 8PE

Sponsor information

Organisation
North Tees and Hartlepool Hospitals NHS Foundation Trust

Sponsor details
Research and development office
1st floor, Middlefield Centre
Stockton on Tees
England
United Kingdom
TS19 8PE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zzrht05

Funder(s)

Funder type
Other

Funder Name
Local R&D incentive funding

Results and Publications

Publication and dissemination plan
Study protocol including other documents will be available on request. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the research and development office (researchanddevelopment@nth.nhs.uk). All de-identified/anonymised data will be available after trial completion after formal request and approval by the local R & D department. This is already included in the patient consent form and participant information leaflet.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	23/11/2020	Yes	No