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Understanding pain and discomfort in preterm babies using artificial intelligence

Submission date 20/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/07/2022	**Overall study status** Completed	
Last Edited 24/08/2022	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
This study aims to explore whether a machine learning tool can better identfy whether babies born before their due date (preterm) who are being looked after in neonatal intensive care units are comfortable or not.

Who can participate?
Babies born at least 4 weeks before their due date (born before 36 weeks gestation) and who are medically stable with consent from their parents.

What does the study involve?
No changes to routine care are involved. Participating babies will undergo video and sound recordings during their normal neonatal care, and computer ratings are compared to the clinical team's assessment of whether the baby was comfortable or not. Machine learning will be used to develop the best algorithm to identify baby discomfort that could be used in the future to alert staff and parents that the baby is uncomfortable.

What are the possible benefits and risks of participating?
Participants will not gain from taking part. There are no risks expected as the researchers are only video recording infants during standard care.

Where is the study run from
Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to August 2023

Who is funding the study?
The Lerverhulme Trust as part of the Newcastle University doctoral training programme in behaviour informatics (UK)

Who is the main contact?
Dr Janet Berrington, janet.berrington1@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
299441

Protocol serial number
IRAS 299441, CPMS 53578

Study information

Scientific Title
Preterm Enhanced Automated Capture Of Comfort Knowledge: the Peacock study

Acronym
PEACOCK

Study objectives
Current observational informatics using state-of-the-art machine learning can better understand whether a newborn baby in an intensive care setting is comfortable or not.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational case series

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Preterm infant discomfort during intensive care

Interventions
The study uses computer learning to evaluate a video of the baby during routine procedures and learns as more cases are observed.

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Intervention Type
Other

Primary outcome(s)
How well the final learning model performs, assessed using machine learning metrics (confusion matrix, accuracy, precision, recall/sensitivity, F1 score, specificity and area under the curve) at the time of the video recording

Key secondary outcome(s))
1. What signal or mixture of signals is most informative of preterm babies' state (face, body, sound and physiological data) at the time of the video
2. What algorithms are best suited for each data stream and why
3. Which methods are best for combining different data streams to make the most accurate estimation of preterm babies' comfort levels
4. Are any of these factors different for some babies e.g. the most immature, those with ventilator devices on their faces
5. Can these models detect prolonged pain (e.g., chronic pain post-surgery), can they distinguish this from acute procedural pain
6. What medical and contextual factors affect behavioural responses to pain
7. How many recordings are required to achieve the best model performance

All will be measured at the time of the video recording and assessed using performance metrics for machine learning outlined in the primary outcome measure

Completion date
01/08/2023

Eligibility

Key inclusion criteria
1. Born at <36 weeks gestation
2. Medically stable
3. Signed parental consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Infants with significant brain, spine or facial congenital abnormality
2. Parents unwilling to provide consent
3. Infants with postmenstrual age >36 weeks

Date of first enrolment
01/08/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Leverhulme Trust

Alternative Name(s)
The Leverhulme Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The researchers do not anticipate making data available routinely as it is complex video and audio and would breach patient confidentiality.

IPD sharing plan summary
Not expected to be made available