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Using parental touch to relieve pain in newborn infants

Submission date
23/08/2021

Recruitment status
No longer recruiting

Registration date
23/08/2021

Overall study status
Completed

Last Edited
25/03/2025

Condition category
Neonatal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Newborn babies who are in hospital sometimes require painful medical procedures to be performed (such as blood tests). The aim of this study is to determine whether parental touch can reduce pain when newborn babies have blood tests.

Who can participate?
Newborn babies and their parents can participate in the trial if their baby needs a blood test while they are in hospital.

What does the study involve?
The study involves measuring the baby's brain activity and other physiological measures (such as heart rate) during the blood test and seeing whether stroking the baby changes the way the baby responds to pain. The researchers also want to know how the parents feel when they participate in their babies care during these procedures.

What are the possible benefits and risks of participating?
The potential benefit for the babies in the study is that they may feel less pain during the clinically required blood test. Parents may also find it less stressful to watch their baby having a blood test if they stroke their baby during the procedure.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2020 to August 2023

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Rebeccah Slater
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Study website
https://neuroimaging.paediatrics.ox.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291213

ClinicalTrials.gov number
NCT04901611

Secondary identifying numbers
CPMS 49904, IRAS 291213

Study information

Scientific Title
A randomised controlled trial to investigate the effects of parental touch on relieving acute procedural pain in neonates

Study objectives
Neonates receiving parental touch of the limb prior to a clinically-required heel lance will have reduced noxious-evoked brain activity compared with neonates receiving post-procedural touch.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 09/08/2021, London - South East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8085, +44 (0)207 104 8104, 0207 104 8265; londonsoutheast.rec@hra.nhs.uk), REC ref: 21/LO/0523

Study design
Randomized; Interventional; Design type: Prevention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Acute procedural pain in neonates

Interventions
Each recruited infant will participate in the trial for approximately 1 hour, and will not require further follow-up. The research team will liaise with the clinical team to identify when the clinically required heel lance is needed and will time the test occasion around this event. Infants will have been randomised to receive parental touch either before, or after, the clinically required heel lance.

At the time of the heel lance, a clinical heel lance and control heel lance stimulus (this is a sham procedure that does not pierce the skin or cause any noxious input) will be performed. In the control heel lance, the lancet is placed against the baby's foot but angled away – when the button is pressed, the sharp inside fires into the air rather than into the baby's foot. This is to simulate the experience of having a blood test without the 'painful' part – i.e. the baby's foot being held by the clinical researcher, the feel of the lancet placed against the foot, and the click sound when the button is pressed and sharp released. There will be a minimum 3-minute gap between the control heel lance stimulus and the clinically-required heel lance.

All outcome measures will be recorded for both the clinical heel lance and control heel lance stimulus.

The parental touch intervention will involve one parent stroking the lower limb of their baby for 10 seconds before/after the control heel lance and clinically-required heel lance. When the intervention is conducted before the heel lance, it will be commenced 10 s prior to the heel

lance. When implemented after the heel lance it will commence after blood collection (minimum of 30 s post heel lance).

At least 30 minutes before the heel lance and control stimulus (and after randomisation), the research team will set up the electroencephalography (EEG), physiological monitoring (electrocardiogram (ECG) – for heart rate and respiratory rate; pulse oximeter – for oxygen saturations), and video monitoring (for facial expression change). Physiological monitoring will continue from approximately 30 minutes prior to the heel lance and control stimulus until approximately 30 minutes afterwards. Noxious-evoked brain activity (measured using EEG) will be recorded for a minimum of 10 minutes prior and 10 minutes after the heel lance and control stimulus. Video monitoring will continue from approximately 30 seconds before to 30 seconds after the heel lance and control stimulus. This is to record facial expression changes during this time period, which are required to calculate the PIPP-R score (clinical pain score incorporating changes in facial expression, heart rate, oxygen saturation and gestational age). The infant's foot will be held by the clinical individual for the duration of the facial video recording for PIPP-R scoring, the stroking intervention, the control heel lance stimulus and the clinically required heel lance. The foot will be held in this manner for infants recruited to either trial arm.

The clinical stability of the infants will be assessed throughout the hour trial period using the physiological recordings. These measures will be calculated from ECG recordings to monitor heart rate and respiratory rate. These data will be monitored and downloaded to our data logging equipment for approximately 30 minutes before and 30 minutes after the heel lance and control stimulus.

Intervention Type
Behavioural

Primary outcome measure
Magnitude of noxious-evoked brain activity following a heel lance measured using EEG data recorded in the 1000 ms period following the procedure

Secondary outcome measures
1. Clinical pain score measured using the Premature Infant Pain Profile-Revised (PIPP-R) score during the 30 s period after the heel lance
2. Development of tachycardia measured using electrocardiogram (ECG) data in the 30 s post-heel lance
3. Parental anxiety assessed using the overall score of a State-Trait Anxiety Inventory (STAI) questionnaire at the start and end of the test occasion

Exploratory outcome measures:
1. Changes in brain activity during touch intervention measured using EEG data recorded in the 1000 ms period following the tactile stimulus
2. Time taken for heart rate measured using ECG data to return to baseline post-heel lance
3. Variability in respiratory rate, incidence of apnoea, and change in respiratory stability measured using physiological data (ECG, pulse oximetry) post-heel lance
4. Investigation of the parental experience of their child's heel lance, general state, and feelings on infant research assessed using scores for individual parameters from the STAI-T and STAI-S; 4-point distress questionnaire score; and responses to survey about participation in Petal and infant research at the start and end of the test occasion

Overall study start date

01/01/2020

Completion date
07/08/2023

Eligibility

Key inclusion criteria
1. Participants born at the John Radcliffe Hospital, Oxford or the Royal Devon and Exeter Hospital, Devon
2. Neonates born at or after 35+0 weeks' gestation
3. Neonates with a postnatal age of 7 days or less
4. Neonates who require a heel lance as part of routine clinical care
5. Neonates for whom parents/guardians have given written informed consent for inclusion in the trial

Participant type(s)
Patient

Age group
Neonate

Upper age limit
7 Days

Sex
Both

Target number of participants
Planned Sample Size: 112; UK Sample Size: 112

Total final enrolment
112

Key exclusion criteria
1. Intraventricular haemorrhage (IVH) > grade II
2. Received any analgesics or sedatives in the last 24 hours
3. Congenital malformation or genetic condition known to affect neurological development
4. Born to mothers who have a history of substance abuse

Added 16/09/2024:
5. Hypoxic Ischaemic Encephalopathy (HIE)

Date of first enrolment
01/09/2021

Date of final enrolment
07/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Devon & Exeter Hospital
Barrack Road
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EX2 5DW

Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust; Grant Codes: 207457/Z/17/Z

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. The study protocol will be submitted for publication
2. Planned publication of the study results in a peer-reviewed journal

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	03/08/2021	23/08/2021	No	No
Statistical Analysis Plan	version 1.0	30/03/2023	31/03/2023	No	No

HRA research summary			28/06/2023	No	No
Protocol file	version 5.0	26/01/2023	11/10/2023	No	No
Results article		21/02/2024	21/02/2024	Yes	No
Results article	Parental experience	25/01/2024	24/02/2024	Yes	No
Results article		18/12/2024	25/03/2025	Yes	No