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Assessing the effectiveness of touch intervention for pain control during examination for retinopathy of prematurity

Submission date
05/03/2020

Recruitment status
No longer recruiting

Registration date
06/03/2020

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Retinopathy of prematurity (ROP) is a disorder of the retinal blood vessels in preterm infants with low birth weight. It is a leading cause of childhood blindness. During ROP screening, the use of mydriatic drops and eyelid openers causes pain and discomfort. Touch intervention is frequently given to relieve procedural pain in neonates. The aim of this study is to investigate the effects of touch intervention on pain in preterm infants undergoing screening for ROP.

Who can participate?
infants in the neonatal intensive care unit at Children's Hospital of Nanjing Medical University who meet the ROP screening criteria

What does the study involve?
infants are randomly assigned to experimental and control groups. The infants in the experimental group continuously receive touch intervention during screening, while those in the control group are screened according to the routine procedure. The touch intervention protocol (Gentle Human Touch) is implemented from the beginning of each procedure until 10 min after the procedure. The neonatologist gently places her left hand on the infant's head with her fingertips resting immediately above the eyebrow line and her palm touching the crown. Her right hand is placed such that the right thumb was on the infant's right shoulder (midline position) and the rest of the hand and fingers are on the infant's arm, above the elbow. The degree of pain during the examination is recorded.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved in taking part in this study.

Where is the study run from?
Children's Hospital of Nanjing Medical University (China)

When is the study starting and how long is it expected to run for?
March 2016 to August 2019

Who is funding the study?
Nanjing Children’s Hospital Affiliated to Nanjing Medical University (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Touch intervention might decrease the pain response during examination for retinopathy of prematurity: a blinded randomized controlled trial

Acronym
TI

Study objectives
Touch intervention might decrease the pain response during examination for retinopathy of prematurity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2016, Children's Hospital of Nanjing Medical University Ethics Committee (72 Guangzhou Road; +86 (0)83117281; nanjingnicu@163.com), ref: #201703069

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Retinopathy of prematurity

Interventions
The research team comprised three research neonatologists, a child health care expert, and three assistants with extensive research and clinical experience. After consent is obtained from parents, infants in the neonatal intensive care unit at Children's Hospital of Nanjing Medical University who met the ROP screening criteria are randomly assigned to experimental and control groups using computer-generated randomization codes. Clinicians, parents, and researchers were blinded to the randomization.

Participants in both groups undergo a range of painful procedures during their ROP Screen in the NICU. The preterm infants in the experimental group continuously receive touch intervention during ROP screening, while those in the control group are screened according to the routine procedure. The touch intervention protocol (Gentle Human Touch) is implemented from the beginning of each procedure until 10 minutes after the procedure. The neonatologist gently places her left hand on the infant's head with her fingertips resting immediately above the eyebrow line and her palm touching the crown. Her right hand is placed such that the right thumb was on the infant's right shoulder (midline position) and the rest of the hand and fingers are on the infant's arm, above the elbow.

The degree of pain is assessed using the Premature Infant Pain Profile (PIPP) score. A double-channel near-infrared spectroscopy device is used to monitor regional cerebral oxygen saturation (rScO2), while oxygen saturation (SaO2) and heart rate (HR) are measured using pulse oximetry. The PIPP score is the primary outcome, while heart rate (HR), SaO2, and rScO2 are secondary outcomes.

Intervention Type
Behavioural

Primary outcome(s)
The degree of pain during the examination quantified using the Premature Infant Pain Profile (PIPP). The PIPP assessment items include the gestational age, increased HR, decreased blood oxygen saturation (SaO2), a state of arousal, and the proportion of painful expressions throughout the examination (frowning, blinking, and wrinkling the nose and sulcus). There are a total of seven items, each of which is scored on a scale of 0–3. The total PIPP score is calculated

as the sum of the scores for all seven items, and the maximum score is 21 points. A higher score indicates greater pain severity. The video camera is positioned for a closeup of the face. The signals were fed directly to a VCR during the painful procedure.

Key secondary outcome(s))
Heart rate (HR), SaO2, and rScO2: an EGOS-600A NIRS meter (EnginMed, Suzhou, China) is used to collect data for the regional cerebral oxygen saturation (rScO2) before and during screening. Before screening, the NIRS probe is placed at the center of the forehead. The recorder traces a 2-min curve in the quiet state, and the stable value displayed after the curve represented the oxygen saturation of the basal brain tissue, which is then compared with the tissue oxygen saturation recorded at the time of pain during ROP screening. At the same time, a pulse oximeter (Comen Medical Instruments, Shenzhen, China) is used to measure SaO2 and HR. For calculation of the PIPP score, the infant's facial expressions and pulse oximetry findings are recorded throughout the procedure.

Completion date
30/08/2019

Eligibility

Key inclusion criteria
1. Premature birth with a gestational age of ≤34 weeks or a birth weight of ≤2000 g
2. No prior history of fundus screening
3. Screening at 4 to 6 weeks of age after birth or a corrected gestational age of 31 to 32 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Administration of nonsteroidal anti-inflammatory drugs or sedative and antiepileptic drugs such as chloral hydrate, phenobarbital, and diazepam within 24 hours before ROP screening
2. Intolerance to screening because of critical conditions like severe respiratory diseases, central nervous system infections, sepsis, and other organic diseases such as severe congenital heart malformation and pulmonary insufficiency
3. Unsuitable conditions during ROP screening, such as severe coughing and shortness of breath

Date of first enrolment
01/01/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
China

Study participating centre
Children's Hospital of Nanjing Medical University
Guangzhou Road 72
Nanjing
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Sponsor information

Organisation
Nanjing Medical University

ROR
https://ror.org/059gcgy73

Funder(s)

Funder type
University/education

Funder Name
Nanjing Medical University (grant no. 2017NJMU058)

Alternative Name(s)
, NMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/12/2020	12/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes