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Pain and hypoxia in premature neonates

Submission date	Recruitment status	[ ] Prospectively registered
18/05/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/05/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/05/2015	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Premature babies (those born at less than 37 weeks gestation) usually need special care in a hospital neonatal intensive-care unit (NICU). This is because they often have serious health problems as a result of being born too early, such as difficulty with breathing and low blood sugar (glucose). As a result, premature babies often need to have an endotracheal tube inserted through their mouth and down their throat to help them breath. They also need frequent blood tests to monitor their health. Therefore, two of the most common routine procedures performed on premature babies in NICUs are suctioning of the endotracheal tube to keep the baby's airway clear, and heel pricks to draw blood samples for glucose (blood sugar) monitoring. Both of these procedures are known to cause some level of discomfort and pain to babies, so on these occasions they are given an oral sugar (sucrose) solution and a dummy (non-nutritive sucking pacifier) to soothe them. Although these procedures are performed repeatedly in the majority of premature babies, their effect on the energy levels of the body's cells are not clear. It is well known that if energy in the cells is low, this can lead to a lack of oxygen in blood and tissue called hypoxia. Hypoxia is known to cause pain and is a very common complication for premature babies due to them not being able to breathe on their own. The aim of this study is to see what effect suctioning of the endotracheal tube and heel prick tests have on energy levels in the cells of premature babies, and will assess the levels of hypoxia-associated pain experienced. The results of this study will be used to inform future studies investigating ways to decrease pain and hypoxia in premature babies.

Who can participate?
Premature babies of less than 36 weeks gestation.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given a sugar (sucrose) solution and a dummy during endotracheal tube suctioning and heel prick procedures. Those in group 2 (control group) are given a non-sugar solution and a dummy during endotracheal tube suctioning and heel prick procedures. Participants have blood tests and pain is assessed using a premature infant pain profile assessment tool.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
1. Loma Linda University Children's Hospital (USA)
2. Riverside County Regional Medical Center (USA)

When is the study starting and how long is it expected to run for?
February 2009 to December 2014

Who is funding the study?
National Institutes of Health (USA)

Who is the main contact?
Dr D Angeles

Contact information

Type(s)
Scientific

Contact name
Dr Danilyn Angeles

Contact details
Loma Linda University
Loma Linda
United States of America
92354

Additional identifiers

Protocol serial number
NR011209-01A1

Study information

Scientific Title
Pain and hypoxia in premature neonates: a randomised controlled trial

Study objectives
Commonly performed tissue damaging procedures exhibit a positive correlation between biobehavioural markers of pain and biochemical markers of hypoxia, oxidative stress and cell injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loma Linda University Institutional Review Board, 25/02/2009, ref: 59038.

Study design

Randomised double-blind placebo controlled trial design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Procedural pain in premature neonates

Interventions
1. Intervention group: sucrose 24% and non-nutritive sucking
2. Control group: placebo and non-nutritive sucking

Intervention Type
Supplement

Primary outcome(s)
1. Pain score
2. Plasma concentration of hypoxanthine, xanthine, uric acid and allantoin

Key secondary outcome(s))
Not applicable.

Completion date
29/12/2014

Eligibility

Key inclusion criteria
Premature infants <36 weeks gestation who:
1. Weigh >800 grams
2. Have an arterial or central line catheter in place
3. Require endotracheal suctioning or heel lance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria

1. Unstable oxygenation and hemodynamic status due to persistent pulmonary hypertension (PPHN)
2. Cyanotic heart disease
3. Severe respiratory distress
4. Septic shock
5. Taking medications such as morphine, fentanyl, versed, muscle relaxants, phenobarbital, or dilantin
6. Intraventricular hemorrhage grade 3 or more
7. Seizures
8. Facial or multiple congenital anomalies that may alter pain behavior

Date of first enrolment
25/02/2009

Date of final enrolment
29/12/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Loma Linda University Children's Hospital
Risley Hall
Loma Linda
United States of America
92354

Study participating centre
Riverside County Regional Medical Center
NICU
Riverside
United States of America
92354

Sponsor information

Organisation
National Institutes of Health, National Institute of Nursing Research

ROR

https://ror.org/01y3zfr79

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes