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A clinical study investigating sucrose as a pain reliever in infants

Submission date 20/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/07/2009	**Overall study status** Completed	
Last Edited 10/11/2010	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
08/0213

Study information

Scientific Title
A doubleblinded randomised controlled study to assess the effect of sucrose versus sterile water on cortical responses to painful events in newborn infants

Study objectives

This is a non-commercial, double-blinded randomised controlled clinical study. The primary objective is to investigate the effects of sucrose versus control (sterile water) on cortical responses to noxious events in newborn infants. The secondary objectives are to examine if sucrose administration will:
1. Induce a change of sleep state
2. Affect an immediate detectable change in blood glucose levels
3. Affect motor activity reflex responses following a noxious event, when compared to control (sterile water) treated groups.
This trial is taking place at the University College London Hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint UCL/UCLH Committees on the Ethics of Human Research Committee Alpha, approved on 30th September 2008 (ref: 08/H0715/74)

Primary study design
Interventional

Study design
Double-blind randomised controlled single centre trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Pain relief following an acute noxious event in newborn infants

Interventions
Subjects will be allocated at random (randomisation ratio: 1:1) to receive one of two 0.5 ml solutions onto the tongue: 24% sucrose water (Sweet-Ease®) or sterile water (control). There is a 50% chance of receiving sucrose. The treatment solution will be administered by a syringe directly into the baby's mouth approximately 2 minutes prior to the heel lance.

The sucrose and placebo will be purchased from Inspiration Healthcare, the manufacturers of Sweet-Ease®. Each recruited subject will participate in a single study and will not require a follow-up. The duration of total participation in the study will take approximately 90 minutes.

Please note that as of 11/02/10 the end date of this trial has been extended from 31/12/09 to 31 /12/2010.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sucrose

Primary outcome(s)
Cortical responses to noxious stimulation using evoked potentials (electroencephalography [EEG])

Key secondary outcome(s)
1. Sleep-state (EEG and video)
2. Blood glucose levels (opportunistically measured from excess blood flow)
3. Motor and facial activity (electromyogram [EMG] and video)

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. In-patients on the labour ward, post-natal ward, transitional care unit (TCU) and special care baby unit (SCBU) at the Elizabeth Garrett Anderson & Obstetrics Hospital, University College London Hospital (UCLH), UK
2. Both males and females, aged between 37 and 45 weeks post-menstrual age (PMA)
Babies will only be studied when a blood test is needed for clinical purposes.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Prior to each study the infant's well-being and their suitability to be studied will be assessed by the clinicians in the research group; studies will be postponed or cancelled if the infant is considered to be unfit to take part.

1. Infants who are asleep
2. Infants who are fed 30 minutes or less before the heel lance
3. Signs of tissue damage on the lower limbs
4. Intraventricular haemorrhage or periventricular leukomalacia
5. Infants who have had previous surgery
6. Infants who are receiving analgesics or sedatives
7. Infants who are born to mothers who are diabetic or opioid users
8. Infants born with congenital malformations or genetic conditions

In addition, infants that fall into the following criteria will be excluded from the study as use of 24% sucrose water is contraindicated:
9. Infants at high risk for necrotising enterocolitis

10. Asphyxiated infants
11. Infants with feeding intolerance
12. Infants without bowel sounds
13. Infants with oesophageal atresia or tracheal oesophageal fistula
14. Infants with active phase persistent pulmonary hypertension of the newborn

Date of first enrolment
25/02/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Elizabeth Garrett Anderson Wing
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK) (ref: G0502146)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/10/2010		Yes	No