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Kangaroo mother care combined with sucrose to reduce pain responses in preterm infants

Submission date 01/10/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/07/2010	**Overall study status** Completed	
Last Edited 20/07/2010	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The efficacy of kangaroo mother care combined with oral sucrose to reduce pain responses in preterm infants: a randomised multicentre clinical trial

Study objectives
1. Is kangaroo mother care combined with sucrose more effective than sucrose alone in reducing the pain responses of preterm infants during venipuncture?
2. How do mothers perceive doing kangaroo care while their infant is having a venipuncture?

Although kangaroo care is effective in reducing the pain responses of preterm infants to procedural pain, the perceptions of mothers of holding their infant skin-to-skin during venipuncture has not been explored.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committees:
1. Comissão de Ética para a Saúde dos Hospitais da Universidade de Coimbra approved on the 9th June 2006
2. Comissão de Ética do Centro Hospitalar de Coimbra approved on the 23rd May 2006

Study design
Multicentre randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Procedural pain during venipuncture

Interventions
1. Oral sucrose with pacifier, 2 minutes before venipuncture
2. Kangaroo mother care during 30 minutes before and during venipuncture plus oral sucrose with pacifier 2 minutes before venipuncture
Infants were followed until discharge from hospital.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Pain responses measured by:
1. Premature Infant Pain Profile Scores
2. Changes in heart rate
3. Changes in oxygen saturation
4. Changes in behavioural state
5. Percentage of time displaying facial actions
6. Heart rate variability
7. Recovery time
Primary outcome measures were taken at baseline (30 seconds before venipuncture); during skin cleansing; needle stick and blood harvesting; compression after needle removal; and rest (up to 5 minutes after the end of the procedure).

Secondary outcome measures
Mothers' perception of doing Kangaroo Care during venipuncture was obtained between one and six days after the venipuncture occurred.

Overall study start date
25/03/2007

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Gestational age between 28 and 36 weeks
2. Postnatal age less than 28 days

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Apgar score less than 6 at 5 minutes
2. Surgery
3. Major congenital anomalies

4. Genetic anomaly
5. Intra-ventricular haemorrhage (IVH) greater than Grade 2 or subsequent periventricular leucomalacia
6. Severe illness as defined by hypo or hyperthermia, need for respiratory support (ventilation or nasal continuous positive airway pressure [CPAP]), inotropic therapy
7. Presence of umbilical catheter
8. Painful procedure in the previous 12 hours
9. Opioid or non-opioid sedation on the 48 hours prior to data collection
10. Diabetic mother
11. Mother with history of substance abuse
12. Mother absent or unable to do kangaroo care for clinical reasons
13. Mother cannot speak/read Portuguese

Date of first enrolment
25/03/2007

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Portugal

Study participating centre
Praceta Falcão Resende, 1, R/Ch
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Sponsor information

Organisation
Nursing School of Coimbra (Escola Superior de Enfermagem de Coimbra) (Portugal)

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Sponsor type

University/education

Website
http://www.esenfc.pt

ROR
https://ror.org/03c3y8w73

Funder(s)

Funder type
Government

Funder Name
Foundation for Science and Technology (Fundação para a Ciência e a Tecnologia [FCT]) (Portugal)

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

Funder Name
Nursing School of Coimbra (Escola Superior de Enfermagem de Coimbra) (Portugal)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration