

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

Submission date 01/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/07/2010	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

Coimbra

Portugal

3000-164

Sponsor information

Organisation

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

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)

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

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Portugal

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary