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Bedding-in on the post-natal ward

Submission date 29/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/01/2006	**Overall study status** Completed	
Last Edited 27/01/2010	**Condition category** Pregnancy and Childbirth	

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
02277

Study information

Scientific Title

Study objectives
That mother-infant sleep proximity on the first two nights of life affects the success of breastfeeding initiation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received 27/09/2002 reference 2002/272

Study design
Randomised non-blinded intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Breastfeeding initiation

Interventions
Control: baby in stand alone cot (rooming in)
Intervention 1 = baby in mother's bed
Intervention 2 = baby in side car crib

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Successful initiation of breastfeeding, defined on the basis of the observed infant behaviours (attempted feeds, successful feeds, feeding effort)

Secondary outcome measures

Infant safety, determined by assessing potential risk exposure: frequency per hour and proportional duration of potentially adverse situations categorised as:
1. Breathing risk (external airways covered)
2. Overheating risk (head completely covered)
3. Falling risk (positioned precariously)
4. Entrapment risk (wedged between bed and side-rail)
5. Overlaying risk (trapped under mothers torso)

Overall study start date
01/10/2002

Completion date
31/03/2005

Eligibility

Key inclusion criteria
Healthy, non-smoking women, pregnant with a single infant, anticipating a normal vaginal delivery and intending to breast feed

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
90

Key exclusion criteria
Post-partum exclusion criteria: caesarean delivery, ill baby or mother and receipt of intravenous or intramuscular opiate analgesics in the preceding 24 hours

Date of first enrolment
01/10/2002

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anthropology
Durham
United Kingdom
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Sponsor information

Organisation
Newcastle Upon Tyne Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Royal Victoria Infirmary
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Project grant from Babes in Arms (10/08/2002) (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2006		Yes	No