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Bedding-in on the post-natal ward

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised non-blinded intervention

Study type(s)
Prevention

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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Department of Anthropology
Durham
United Kingdom
DH1 3HN

Sponsor information

Organisation
Newcastle Upon Tyne Hospitals NHS Trust (UK)

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

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