

Bedding-in on the post-natal ward

Submission date 29/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
DH1 3HN

Sponsor information

Organisation

Newcastle Upon Tyne Hospitals NHS Trust (UK)

Sponsor details

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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