# Bedding-in on the post-natal ward

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

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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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

#### Study design

Randomised non-blinded intervention

#### Primary study design

Interventional

#### 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**

# 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