

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of breastfeeding on pain relief in full-term neonates during B vaccination

#### Protocol summary

##### Summary

Healthy neonates routinely are undergoing painful minor procedures. The aim of this study was to explore the effect of breastfeeding and pain relief in full-term neonates during injection of hepatitis B vaccination. This was a randomized clinical trial. A sample of full-term neonates were randomly allocated into two groups: the experimental group (group 1) and the control (group 2). Neonates in the experimental group were breastfed two minutes before, during, and after the hepatitis B immunization and group 2 were held in mothers' arms but not fed. Pain was assessed using the Douler Aigue Nouveaune (DAN) scale measuring facial expressions, limb movements and vocal expressions. The assessments were carried out after hepatitis B immunization. Criteria for inclusion were: full-term neonate; had APGAR scores 7 higher at five minutes after birth; delivered by spontaneous and vaginal delivery; were breastfed; postnatal age not more than 24 hours. We excluded infants with any evidence of congenital abnormalities, medical complications, or drug exposure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104166206N1**  
Registration date: **2011-04-26, 1390/02/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-26, 1390/02/06

##### Registrant information

**Name**

Parvin Rahnama

##### Name of organization / entity

Shahed University

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2007-11-12, 1386/08/21

##### Expected recruitment end date

2008-03-29, 1387/01/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of breastfeeding on pain relief in full-term neonates during B vaccination

##### Public title

The effect of breastfeeding on pain relief in newborns during vaccination

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Criteria for inclusion were: full-term neonate; had APGAR scores 7 higher at five minutes after birth; delivered by spontaneous and vaginal delivery; were breastfed; postnatal age not more than 24 hours. We excluded infants with any evidence of congenital abnormalities, medical complications, or drug exposure.

**Age**

To 24 years old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 130

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences.

**Street address**

Ghods St, Keshavarz Blv, Tehran University of Medical Sciences

**City**

Tehran

**Postal code****Approval date**

2007-09-10, 1386/06/19

**Ethics committee reference number**

250/4812

**Health conditions studied****1****Description of health condition studied**

pain during hepatitis vaccination

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

facial expressions, limb movement, vocal expressions

**Timepoint**

after vaccination

**Method of measurement**

observation

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the intervention group: Participating neonates and their mothers were taken to a quiet nursery room for immunization. The study did not start until the infant was observed to be sucking at the breast. Effective sucking movements were defined as movements in which the sucking sufficiently moved the temporomandibular joints to allow the infant to obtain maternal milk and eventually swallow it. This usually required 30-60 seconds to achieve. None of the infants had been breastfed for at least 30 minutes before the study procedures commenced. In experimental group, feeding was begun two minutes before, during, and after hepatitis B vaccination (n=65). At the end of the second minute of breastfeeding, while the infants were still sucking, the immunization injections were performed.

**Category**

Prevention

**2****Description**

In the control group: neonates were not breastfed but held by the mother for the same length of time at the experimental group. In the controls experienced the same procedure while were held in mothers arms but not fed.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mirzakochak Khan ( women hospital)

**Full name of responsible person****Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotohi

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Ghods St, Keshavarz Blv,

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*