Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 exprssions
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
Street address
Ghods St, Keshavarz Blv,
City
Tehran
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

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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