Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of breast feeding, sucking the pacifier and being in mother's hug on pain during infant's immunization injection

Protocol summary

Summary

The objective of this study was to examine the pain relieving effect of breast-feeding, pacifier use or being in mother's hug and routine of health centers clinics during immunization injections in healthy neonates. This controlled trial study, was performed on 152 healthy term infants with 2- 4 months old, which was brought to the health centers of Iran University of Medical Sciences in west of Tehran by their mother and had DPT immunization. One group were breast-fed, 2 minutes before, during, and 15 seconds after the injection, and second group were used pacifier while held by mothers, 2 minutes before, during, and 15 seconds after the injection, third group were in their mother's hug 2 minutes before, during, and 15 seconds after the injection and control group according to routine clinic lied on the examining table. Objective changes in appearance of Neonates were assessed by Modified Behavioral Pain Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008284002N2**
Registration date: **2010-09-23, 1389/07/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-23, 1389/07/01

Registrant information

Name

Shadab Shahali

Name of organization / entity

Academic centre of education, culture and research (ACECR), Iran University of medical sciences bran

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of breast feeding, sucking the pacifier and being in mother's hug on pain during infant's immunization injection

Public title

Comparison of the effect of breast feeding, sucking the pacifier and being in mother's hug on pain during infant's immunization injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion/Exclusion: 1. neonate should be awake 2. Neonate pad shouldn't be wet 3. neonate used to breast feed and suck pacifier 4. Neonate or its mother shouldn't use sedative drugs for 48 hours 5. Neonate shouldn't be fed 30 minutes before DPT vaccination 6. Neonate shouldn't be hospitalized for disease or surgery.

Minimum age: 2 month, Maximum age: 4 month

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemmat high way

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

498

Health conditions studied

1

Description of health condition studied

prevention of pain

ICD-10 code

Z00-Z99

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

pain relieving

Timepoint

2 minutes before, during, and 15 seconds after the injection

Method of measurement

Modified Behavioral Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

First group were breast-fed, 2 minutes before, during, and 15 seconds after the injection

Category

Prevention

2

Description

Third group were in their mother's hug 2 minutes before, during, and 15 seconds after the injection

Category

Prevention

3

Description

Second group were used pacifier while held by mothers, 2 minutes before, during, and 15 seconds after the injection

Category

Prevention

4

Description

Control group according to routine clinic lied on the examining table

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in west of Tehran

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
DR. Seid Abbas Motevalian
Street address
Hemmat highway, near Milad Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shadab Shahali
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Person responsible for scientific inquiries

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Simin Taavoni
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Person responsible for updating data

Contact
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Shadab Shahali
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Postal code
Phone
Fax
Email
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