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

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

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
+98 21 8879 7403

Email address
shahali@irmed.org
**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**

<table>
<thead>
<tr>
<th>Ethics committee</th>
<th>Name of ethics committee</th>
<th>Street address</th>
<th>City</th>
<th>Approval date</th>
<th>Ethics committee reference number</th>
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<tr>
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<td>Iran University of Medical Sciences</td>
<td>Hemmat high way</td>
<td>Tehran</td>
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**Health conditions studied**

<table>
<thead>
<tr>
<th>Description of health condition studied</th>
<th>ICD-10 code</th>
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<tbody>
<tr>
<td>prevention of pain</td>
<td>Z00-Z99</td>
<td>Factors influencing health status and contact with health services</td>
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**Primary outcomes**

<table>
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<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
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<td>pain relieving</td>
<td>2 minutes before, during, and 15 seconds after the injection</td>
<td>Modified Behavioral Pain Scale</td>
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**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**
Health centers in west of Tehran

**Sponsors / Funding sources**

1. **Sponsor**
Iran University of Medical Sciences

**Grant name**
Hemmat highway, near Milad Hospital

**Grant code / Reference number**
Tehran
<table>
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<th>Question</th>
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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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- **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