Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of the breastfeeding and sugar water on vaccination pain in infants

Protocol summary

Summary

This study is a double-blind clinical trial that was performed In order to compare the effect of oral glucose with breastfeeding on pain of vaccination in infants. The study population were 195 healthy infants aged 2, 4, or 6 months referred to health centers of Yasuj city to receive DPT vaccine. The infants were randomly allocated into three groups. In the first group, the infants received breastfeeding started two minutes before injection of DPT vaccine and continued until the completion of injection. The other group received 2 cc of 50 percent glucose, orally by syringe. Control group didn’t receive any intervention and stayed in the mother's arms. Children's behavioral responses were observed 5 seconds before to 15 seconds after the injection according to modified behavioral pain by two observers unaware of the type of intervention. The duration of crying in seconds was recorded until 3 minutes after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905124359N2**
Registration date: **2010-09-01, 1389/06/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-01, 1389/06/10

Registrant information

Name

Leila Nikrooz

Name of organization / entity

Yasouj Univercity Medical Siencese

Country

Iran (Islamic Republic of)

Phone

+98 74 1223 4115

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2005-06-20, 1384/03/30

Expected recruitment end date

2005-08-11, 1384/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of the breastfeeding and sugar water on vaccination pain in infants

Public title

Comparing the effect of the breastfeeding and sugar water on vaccination pain in infants

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: being healthy, age 2, 4, 6 months, breastfed Exclusion criteria: having a crying grade 3, receiving analgesic 48 hours prior to the intervention, receiving nutrition 30 minutes prior to the intervention, having a history of surgery, having a chronic disorder

Age

From **2 years** old to **6 years** old

Gender

Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **195**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahwaz Jondi Shapur University of Medical Sciences,
Street address
Golestan, Ahwaz
City
Ahwaz
Postal code
Approval date
2005-06-18, 1384/03/28
Ethics committee reference number
2387/20/8/پ

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52, Y60.3
ICD-10 code description
Acute pain, During injection or immunization

Primary outcomes

1

Description
Behavioral pain responses
Timepoint
5 seconds before injection until 15 seconds after injection
Method of measurement
Modifed Behavior Pain Scale

Secondary outcomes

1

Description
Duration of crying
Timepoint
Start of injection to calm down infants up to 3 minutes after injection
Method of measurement
cornometr

Intervention groups

1

Description
Breast feeding starting and continued until the injection
Category
Prevention

2

Description
No intervention, infants kept in the mother’s arm
Category
N/A

3

Description
Glucose, 50%, 2 cc, orally 2 minutes before DPT vaccination
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Yasuj
Full name of responsible person
Street address
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz Jondi Shapur University of Medical Sciences,
Full name of responsible person
Shahnaz rostami
Street address
Golestan, Ahwaz
City
Ahwaz
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz Jondi Shapur 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
Yasuj Univercity of Medical Sience
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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