

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Email address

l-nikrooz@yums.ir

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

Modified 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 University of Medical Science
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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