

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of oral sucrose , breastfeeding and combination method on decreasing the first injective vaccines local pain in infants

Protocol summary

Summary

Goal: The comparison of oral sucrose, breastfeeding and combination method on decreasing the first infant immunization local pain in health centres of Tabriz-Iran in 2009. Study sample: 120 infant (under 3 month in age) referring to Tabriz Health centres. Intervention: this study involved 3 intervention groups and one control group. First, Infant pain controlled by using NIPS checklist, then randomly samples classified into four groups, 0.6 cc/kg sucrose 25% was given to first intervention group, in the second group infants were breastfed, duration of breastfeeding was based on the infant's reluctant. In the third group breastfeeding was done at first and then 0.6 cc/kg sucrose 25% was given. In control group there was no intervention. Two minutes after intervention vaccination was done, and then pain, crying duration and heart pulse number were controlled in 0, 5th and 10th minutes.

Iran (Islamic Republic of)

Phone

+98 914 313 5837

Email address

sahebihagh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sceinces

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-08-22, 1388/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802101864N1**

Registration date: **2010-09-21, 1389/06/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-21, 1389/06/30

Registrant information

Name

Mohammad Hassan Sahebihagh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Scientific title

The comparison of oral sucrose , breastfeeding and combination method on decreasing the first injective vaccines local pain in infants

Public title

Effect of oral sucrose and breastfeeding on decreasing pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Infants were under 3 old months. 2. Infants were eligible for receiving first time injective vaccines. 3. Infants had no diseases. 4. Infants had acceptable weight (3-97 percentiles) 5. Infants' parents were satisfied to participate in research. 6. Infants didn't receive sweet food 30 minutes before vaccination. 7. Infants weren't born from diabetic mothers. 8. Infants didn't receive drugs before vaccination especially acetaminophen. 9. Infants were fullterm. 10. Infants

weren't breastfed or received pacifier at least 30 minutes before vaccination. 11. Infants' mothers did not have any limitations for breastfeeding. 12. Infants' mothers didn't receive drugs. 13. Infants should have vaccination injection pain experiment. 14. Infants could come to health center with their mothers. Exclusion criteria: 1 - Parents' non-tendency to take part in research process in every stage of study. 2- Breastfeeding from starting infants' monitoring until pain control in 10th minute in control and sucrose groups. 3 - Intensive and long crying which is caused by DPT vaccine, not by pain injection.

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

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

Tabriz University of Medical Sciences

Street address

Vice Chancellor for researchr, No. 2 central building of Tabriz University of Medical Sciences, Daneshghah Ave.

City

Tabriz

Postal code

5166615731

Approval date

2009-06-01, 1388/03/11

Ethics committee reference number

2568/4/5

Health conditions studied

1

Description of health condition studied

Pain after first time vaccine injection

ICD-10 code

T88.1

ICD-10 code description

Other complications following immunization, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

pre-intervention, immediately after intervention, 5th and 10th minutes after intervention

Method of measurement

NIPS (Neonatal Infant Pain Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 0.6 cc/kg sucrose 25%

Category

Prevention

2

Description

Control group: no intervention.

Category

N/A

3

Description

Intervention group 3: at first breastfeeding was done and then 0.6 cc/kg sucrose 25% was given.

Category

Prevention

4

Description

Intervention group 2: infants were breastfed; duration of breastfeeding was based on the infant's reluctant.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Eram and shahidan Ebrahimi Health Centers

Full name of responsible person

Mohamad Hasan Sahebihagh

Street address

Health Group, Nursing and midwifery Faculty, South Shariaty

City

Tabriz

City

Tabriz

Postal code

5138947977

Phone

+98 41 1479 6770

Fax

+98 41 1479 6969

Email

sahebihagh@tbzmed.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of Medical Sciences

Full name of responsible person

Dr. Mohamad Reza Rashidi

Street address

Research Department, 3rd floor of 2nd central bulding of Tabriz university of Medical Sciences, Daneshghah Ave.

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz university of Medical Sciences

Full name of responsible person

Mohamad Hasan Sahebihagh

Position

Master Science in Community Health Nursing and Nursing Management

Other areas of specialty/work

Street address

Health Group, Nursing and midwifery Faculty, South Shariaty

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Hasan Sahebihagh

Position

Master Science in Community Health Nursing and Nursing Management

Other areas of specialty/work

Street address

Health Group, Nursing and midwifery Faculty, South Shariaty

City

Tabriz

Postal code

5138947977

Phone

+98 41 1479 6770

Fax

+98 41 1479 6969

Email

sahebihagh@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Mohamad Hasan Sahebihagh

Position

Other areas of specialty/work

Street address

City

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