Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Oral sucrose, Distraction and application of oral sucrose and distraction together on pain infants immunization injection

Protocol summary

Summary

The aim of current study was to examine the effect of distraction technique and oral sucrose in reducing pain due to vaccination. inclusion criteria was awake and silent of infant with score pain maximum ,pad infand dried , absence of confiend to bed hospital casuse medical or surgical , absence of cold or diearrhea time of vaccination , term baby , abcence of recive analgesic before 48 hours vaccination and exclusion criteria was mother not permitted is continous intervention , mother interrest to embrance baby before of finishing intervention and evaluation . this controlled trial study was performed on 152 healthy infants that were randomly assigned to distraction technique (n=38), oral sucrose(n=38) and application of oral sucrose and distraction together(n=38) and routine care(n=38).For Infants in distraction group, investigator provided distraction(Rattle), 30 second before, during, and 15 second after the injection, infant in sucrose group received 2 ml oral sucrose 2 minute before injection, and together group received 2 ml oral sucrose 2 minute before injection and after 90 second investigator provided distraction(Rattle) to 15 second after injection , and control group according to routine clinic lied on the examining table. The results showed that the MBPS scores were significantly lower in distraction group and sucrose groupand both groups compared with the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809012751N1**
Registration date: **2012-11-26, 1391/09/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-11-26, 1391/09/06

Registrant information

Name
Masoomeh Kheirkhah
Name of organization / entity
Iran university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8247 1000
Email address
kheirkhah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Oral sucrose, Distraction and application of oral sucrose and distraction together on pain infants immunization injection

Public title

Comparison of the effect of oral sucrose, distraction and application of oral sucrose and distraction together on pain infants immunization injection, health centers of West Tehran 2009 ”

Purpose
Supportive
Inclusion/Exclusion criteria
inclusion criteria : 1- awake and silent of infant with score pain maximum 3 2- pad infand dried 3- absence of confiend to bed hospital casuse medical or surgical 4- absence of cold or diearrhea time of vaccination 5- term baby 6- abcence of recive analgesic before 48 hours vaccination exclusion criteria : mother not permitted is continous intervention 2- mother interrest to embrance baby before of finishing intervention and evaluation .
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 Univercity of Medical Science and Health Services
Street address
Shahid Easami St, Vanak avenue, Faculty Nursing and Midwifery
City
Tehran
Postal code
Approval date
2009-06-16, 1388/03/26
Ethics committee reference number
1289503

Health conditions studied

1

Description of health condition studied
Persons encountering health services for examination and investigation
ICD-10 code
Z00.6
ICD-10 code description
Examination for normal comparison and control in clinical research programme

Primary outcomes

1

Description
The Effect of Distraction Technique and Oral Sucrose in Reducing pain due to Vaccination.
Timepoint
During 5 second before immunization to 15 second after
Method of measurement
Modified Behavioral Pain Scale (MBPS)

Secondary outcomes

1

Description
Reduce of on pain due to vaccination injection
Timepoint
Reduce of on pain due to vaccination injection
Method of measurement
Reduce of on pain due to vaccination injection

Intervention groups

1

Description
Effect of oral sucrose, distraction and application of oral sucrose and distraction together on pain due to vaccination injection,
Category
Prevention

2

Description
2 ml oral sucrose25% among 30 second with niddle and 2fter 2 min vaccination injection doing in intervention isucrose group received
Category
Prevention

3

Description
30 second before, during, and 15 second after the injection Rattle in used.
Category
Prevention

4

Description

Both groups received 2 ml oral sucrose 2 minute before injection and after 90 second investigator provided distraction(Rattle) to 15 second after injection

Category

Prevention

5

Description

Control group according to routine clinic lied on the examining table

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of West Tehran

Full name of responsible person

Honarvari

Street address

Ostad moin st, Dastgib st, Health Centers of West Tehran, Tehran . Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran university of Medical Science and Health Services

Full name of responsible person

Mazear Moradi Laleh

Street address

Hemmat great way , Iran University Medical Science

City

Tehran

Grant name

Grant code / Reference number

777/پ

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

Yes

Title of funding source

Iran university of Medical Science and Health Services

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Science and Health Services

Full name of responsible person

Masoomeh Kheirkhah

Position

Master Science

Other areas of specialty/work

Street address

Easami st , Vanak ave, Faculty Nursing and Midwifery

City

Tehran

Postal code

1438783941

Phone

+98 21 8801 3887

Fax

Email

m-kheirkhah@tums.ac.ir

Web page address

Person responsible for updating data

Contact

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