

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 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

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##### 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 infant dried 3- absence of confied to bed hospital casuse medical or surgical 4- absence of cold or diarrhea time of vaccination 5- term baby 6- absence of recive analgesic before 48 hours vaccination exclusion criteria : mother not permitted is continous intervention 2- mother interest 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**

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**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