Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Impact of Distraction Technique on Reducing the Infant's Pain due to Immunization

Protocol summary

Summary

Infants routinely undergo painful procedures, such as immunization injection and heel lancing. Therefore, recognition and application of pain control strategies by health care worker is necessary. The objective of this study is to assess the effect of distraction on immunization injection pain in infants. This study is a randomized controlled trial that will be performed on healthy infants, who will be brought to Sajadshahr health center of birjand University of Medical Sciences by their mother and have DPT immunization. 80 healthy infants were randomly will assigne to experimental and control groups.During immunization, experimental group will receive a rattle as a distraction technique by the researcher 45seconds before vaccination until 15 seconds after, while the control group will receive standard care in health centers. The modified behavioral pain scale (MBPS) and cry time will use to assess pain scores 15 second after immunization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107277130N1**
Registration date: **2012-03-21, 1391/01/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-21, 1391/01/02

Registrant information

Name

Zahra Younesi

Name of organization / entity

Birjand University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 0550

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2012-01-10, 1390/10/20

Expected recruitment end date

2012-06-09, 1391/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Distraction Technique on Reducing the Infant's Pain due to Immunization

Public title

The Impact of Distraction Technique on Reducing the Infant's Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Breast feeding is the dominant; birth is term (37-42); Child's growth curve is normal; the child is quiet and without crying; child and mother have not received analgesia or sedative medications during 48h prior to the study; Infant diaper is dry; infant is eligible for DPT vaccination. Exclusion criteria: Child has history of surgery, hospitalization; Child with cerebral palsy and is mentally retarded; Child has acute or chronic illness.

Age
To **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Ghaffari Street
City
Birjand
Postal code
Approval date
2011-10-04, 1390/07/12
Ethics committee reference number
58415/125

Health conditions studied

1

Description of health condition studied
immunization injection pain in infants
ICD-10 code
Z27.1
ICD-10 code description
Need for immunization against diphtheria-tetanus-pertussis, combined [DTP]

Primary outcomes

1

Description
pain
Timepoint
15 seconds after vaccination
Method of measurement
modified behavioral pain scale (MBPS)

2

Description
cry time
Timepoint
Injection until the end of time crying
Method of measurement
seconds

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group will receive a rattle as a distraction technique by the researcher, 45 seconds before vaccination until 15 seconds after that.
Category
Other

2

Description
Control group will receive standard care in health centers.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sajadshahr Health Center
Full name of responsible person
Zahra Younesi
Street address
Sajadshahr Health Center, Sajadshahr
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohamad Darmiani
Street address
Birjand University of Medical Sciences, Ghaffari Street

City
Birjand
Grant name
Grant code / Reference number
496
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
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Position
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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