Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

An Integration of Vibration and Cold Relieves immunization Pain injection in infants

Protocol summary

Summary
Immunization is a common painful event during infancy, which is typically performed without pain control. Regarding Importance of pain control in children, the purpose of this study was to investigate the effectiveness of An Integration of Vibration and Cold Relieves immunization Pain injection in infants.: In this clinical trial of six-month-old infants who will referred to sajadshahr health center of birjand University of Medical Sciences, 80 infants will randomized assigned to experimental and control groups, Vibrator,cool means will be placed over the injection site one minute before and 15 seconds after DTP vaccination , while the control group will receive standard care in health Center. Symptoms associated with pain will evaluate using the modified behavioral pain scale (MBPS), crying time.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201207157130N2**
Registration date: **2014-09-25, 1393/07/03**
Registration timing: **prospective**

Last update:
Update count: **0**
Registration date
2014-09-25, 1393/07/03

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
z-unesi@bums.ac.ir

Recruitment status
Recruitment complete
Funding source
Birjand University of Medical Sciences

Expected recruitment start date
2015-01-01, 1393/10/11
Expected recruitment end date
2015-05-01, 1394/02/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
An Integration of Vibration and Cold Relieves immunization Pain injection in infants

Public title
An Integration of Vibration and Cold Relieves Pain in infants
Purpose
Prevention
Inclusion/Exclusion criteria
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
From **6 months** old to **6 months** 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
Ethics Committee of Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, school in Nursing and Midwifery, Ghaffari Street
City
Birjand
Postal code
Approval date
2014-06-26, 1393/04/05
Ethics committee reference number
44490/25

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)

Secondary outcomes

1

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

Intervention groups

1

Description
Vibrator,cool means will be placed over the injection site one minute before and 15 seconds after DTP vaccination
Category
Other

2

Description
the control group will receive standard care in health Center.
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 Birjand ,South Khorasan
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of birjand University of Medical Sciences
Full name of responsible person
Mohamad Darmian
Street address
Birjand University of Medical Sciences, Ghaffari Street
City
Birjand
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of 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
Zahra Younesi
Position
MS in Nursing
Other areas of specialty/work
Street address
Birjand University Of Medical Sciences, Ghaffari Street
City
Birjand
Postal code
Phone
+98 56 1444 0550
Fax
+98 56 1444 0550
Email
z-unesi@bums.ac.ir , unesi500@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University Of Medical Sciences
Full name of responsible person
Zahra Younesi
Position
MS in Nursing
Other areas of specialty/work
Street address
Birjand University Of Medical Sciences, Ghaffari Street
City
Birjand
Postal code
Phone
+98 56 1444 0550
Fax
+98 56 1444 0550
Email
z-unesi@bums.ac.ir , unesi500@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Zahra Younesi
Position
MS in Nursing
Other areas of specialty/work
Street address
Birjand University Of Medical Sciences, Ghaffari Street
City
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Postal code
Phone
+98 56 1444 0550
Fax
+98 56 1444 0550
Email
z-unesi@bums.ac.ir , unesi500@yahoo.com
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