Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of breastfeeding mothers and sensorial saturation on the physiological parameters and behavioral pain responses in infants after Pentavalent vaccine injection in 4 and 6 months.

Protocol summary

Summary

The aim of study is to evaluate and Comparison of the effect of breastfeeding mothers and sensorial saturation on the physiological parameters and behavioral pain responses in infants after Pentavalent vaccine injection in 4 and 6 months. 180 infants will be divided randomly into three groups of breast-feeding by the mother (Group 1) , sensory saturation (Group 2) and control group (Group 3). Inclusion criteria: No history of hospitalization, Having chronological age 4 months, Awake and calm infants and legal guardian 's consent intervention. Exclusion criteria : Cancel the legal guardian of continued cooperation in the project, Awareness of an infant developing chronic diseases during the two months between two stage intervention and complications attributed to the pertussis vaccine Pentavalent four months after vaccination. Population of the study is all 4 -month-old infants referring to health centers Yasouj Dastgheib martyr. Total sample size is 180 infants who will be divided into three groups of 60 people. Intervention group 1: Two minutes of breastfeeding to infant. Intervention group 2: Stimulate the five senses infants for two minutes. Group 3 will be the control group. Data collected four months after the first minute Vaccination and in the second phase of the project after two months, later on same infants with full respect for the conditions before the intervention , will be. Then Data will be collected again. Primary outcome are Physiological parameters, behavioral pain responses infants and crying time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051527916N1**

Registration date: **2016-06-17, 1395/03/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-17, 1395/03/28

Registrant information

Name

Narges Kazemi Karani

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7251

Email address

narges.kazemi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of breastfeeding mothers and sensorial saturation on the physiological parameters and behavioral pain responses in infants after Pentavalent vaccine injection in 4 and 6 months.

Public title

Comparison of the effect of breastfeeding mothers and sensorial saturation on Pain in infants after vaccination.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: No history of hospitalization due to illness or surgery in infants; Having chronological age 4 months; Do not receive Analgesic for 48 hours before vaccination by the mother and infant; Having a dominant fed with breast milk; Lack of feed for 30 minutes before vaccination; Awake and calm infants; Dry diaper for infants; Lack of cold or diarrhea, immunization; Infant being healthy and lack chronic disorder; No history of respiratory diseases and respiratory allergies; No history of hypersensitivity to lavender; Legal guardian 's consent intervention. Exclusion criteria : Cancel the legal guardian of continued cooperation in the project; Awareness of an infant developing chronic diseases during the two months between two stage intervention; The infant admitted to the hospital during the two months between two stage intervention; Complications attributed to the pertussis vaccine Pentavalent four months after vaccination; Infant respiratory symptoms and skin allergy.

Age

To **6 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Yasuj University of Medical Sciences

Street address

Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd., Yasuj, Iran Yasuj

City

Yasuj

Postal code

7591994799

Approval date

2016-04-30, 1395/02/11

Ethics committee reference number

IR.YUMS.REC.1395.20

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

physiological parameters, including: Respiratory rate , heart rate , arterial oxygen saturation

Timepoint

The first minutes vaccine four and six months

Method of measurement

heart rate and arterial oxygen saturation by pulse oximetry . By counting the number of breaths by a research assistant

2

Description

Behavioral pain responses in infants

Timepoint

The first minutes vaccine four and six months

Method of measurement

behavioral pain responses infants adjusted by Modified Behavioral Pain Scale (MBPS)

3

Description

Crying time

Timepoint

The infant until smooth

Method of measurement

Crying time in seconds by stopwatch

Secondary outcomes

empty

Intervention groups

1

Description
Interventions 1: Breast-feeding by the mother to the infant will be for two minutes .
Category
Other

2

Description
Interventions 2: Senses of taste , smell , touch, sight and hearing of infants respectively by 2 ml 50% dextrose , two drops of lavender, massage the face and back , Look out for face and gentle talk will stimulate the infant .
Category
Other

3

Description
Control group: In this group there will be no intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center Shahid Dastgheib
Full name of responsible person
Ebrahim Momeni
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Yasuj University of Medical Sciences
Full name of responsible person
Doctor Mehdi Akbartabar turi
Street address
Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd.
City
Yusuj
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,Yasuj 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
Yasuj University of Medical Sciences
Full name of responsible person
Ebrahim Momeni
Position
Master of Science in Community Health Nursing Training-coach
Other areas of specialty/work
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj
City
Yasuj
Postal code
Phone
+98 74 3323 5141
Fax
Email
momeni.ebrahim@yums.ac.iremomeni126@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yasuj University of Medical Science
Full name of responsible person
Ebrahim Momeni
Position
Master of Science in Community Health Nursing Training
Other areas of specialty/work
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj
City
Yasuj

Postal code
Phone
+98 74 3323 5141
Fax
Email
momeni.ebrahim@yums.ac.iremomeni126@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yasuj University of Medical Science
Full name of responsible person
Narges Kazemi Karani
Position
MS student of Community Health Nursing
Other areas of specialty/work
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj
City
Yasuj
Postal code
Phone
00
Fax
Email
narges.kazemi@yums.ac.irkazeminarges93@gmail.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