

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

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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.		Ethics committee of Yasuj University of Medical Sciences	
Public title	Comparison of the effect of breastfeeding mothers and sensorial saturation on Pain in infants after vaccination.	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
Purpose	Supportive	City	Yasuj
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.	Postal code	7591994799
Age	To 6 months old	Approval date	2016-04-30, 1395/02/11
Gender	Both	Ethics committee reference number	IR.YUMS.REC.1395.20
Phase	N/A	Health conditions studied	
Groups that have been masked	No information	1	
Sample size	Target sample size: 180	Description of health condition studied	
Randomization (investigator's opinion)	Randomized	pain	
Randomization description		ICD-10 code	
Blinding (investigator's opinion)	Not blinded	R52.0	
Blinding description		ICD-10 code description	
Placebo	Not used	Acute pain	
Assignment	Parallel	Primary outcomes	
Other design features		1	
Secondary Ids		Description	
empty		physiological parameters, including: Respiratory rate , heart rate , arterial oxygen saturation	
Ethics committees		Timepoint	
1		The first minutes vaccine four and six months	
Ethics committee		Method of measurement	
Name of ethics committee		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

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Position

Master of Science in Community Health Nursing
Training-coach

Other areas of specialty/work

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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