Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Survey the Effect of Foot Reflexology on Physiological Indices, Pain Level and Crying of Infants under Vaccination

Protocol summary

Study aim
Determination the effect of foot reflexology on physiological indices , pain level and crying of infants under vaccination

Design
Clinical trial with control and sham groups, With parallel groups, one blind randomized, with 90 samples

Settings and conduct
Comprehensive health venter number 7 in Rasht;In the intervention group each leg will undergo a general massage in order to warm up,for one minute.Then the researcher will massage the area of the thighs on the foot of each foot for 15 minutes (a total of 30 minutes per infant).The infants of the sham group will receive massage at the neutral point (under the ankle foot).For the control group, the vaccine will be performed without any intervention, as usual in the center; participate does not know which of the three groups belong.

Participants/Inclusion and exclusion criteria
Entry criteria:Age 2 to 7 months, being in a normal percentile of weight and height growth when receiving a vaccine, being term , to be calm and crying infant before receiving the vaccine, not taking acetaminophen or any other analgesic drug 3 hours before vaccination, not having a history of hospitalization, Lack of diseases such as thyroid disorders, epilepsy, Cardiovascular disease and acute disease that reduces the level of consciousness of the child, not have bad sleep or sleeplessness before inject the vaccine,the temperature between 37.2-36 °

Intervention groups
In the intervention group each leg will undergo a general massage in order to warm up.Then the researcher will massage the area of the thighs on the foot of each foot .The infants of the sham group will receive massage at the neutral point (under the ankle foot).For the control group, the vaccine will be performed without any intervention, as usual in the center

Main outcome variables
Pain level, physiological indices (heart rate and arterial oxygen saturation), crying time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130412012990N10**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **prospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date
2019-06-15, 1398/03/25

Registrant information

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Name of organization / entity
Guilan University of Medical Sciences and Health Services

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey the Effect of Foot Reflexology on Physiological Indices, Pain Level and Crying of Infants under Vaccination

Public title
Survey the Effect of Foot Reflexology on Physiological Indices, Pain Level and Crying of Infants under Vaccination
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age 2 to 7 months Being in a normal percentile of weight and height when receiving vaccine was born term (38-42 weeks gestation) to be calm and not crying before vaccination Body temperature between 36- 37. 2° C
Exclusion criteria:
Not taking acetaminophen or any other analgesic 3 hours before vaccination Not having a history of hospitalization Lack of diseases such as thyroid disorders, epilepsy, cardiovascular disease and acute diseases that reduces the level of consciousness of the child. Not having bad sleep or sleeplessness before vaccination
Age
From **2 months** old to **7 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, samples with entry criteria will be census sampled and Then randomly sampled using ABCABC permutation blocks with six blocks.As the letter "C" as the control group, the letter "B" will be considered as the sham group and the letter "A" will be considered as the intervention group.Blocks will be recorded and drawn in all possible scenarios.So that each lottery block is randomly selected and the block obtained after registration is returned to the lottery box.Sampling will continue to reach the sample size determined in each group (30 people). To create sequences after registering different states and possible three letters A, B and C in blocks 6 and placement of each letter in separate sheets, placed in the next step of the paper in the container and using a lottery randomly each time one of the sheets was dropped out of the container and the letters on it were written in sequence, and the desired sheet was returned to the container again.The number of times the lottery will be determined after specifying the sample number will be specified,So that Each time the letters on the tab will be added along with the previous letters in the same order.To create random assignments, the following software can also be used: Random allocatin software. The next step is to hide the closed envelopes.In such a way that each of the designated letters is assigned a number to the number of specified sample sizes and the letter is placed inside an envelope and the number of that letter will be written on the envelope. The method of assigning samples to each intervention, sham and control group is that by selecting any infant who has the criteria for entering the study, one of these packs will be opened, respectively, the word in the envelope indicates that infant should be in which of the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participant does not know which of the three groups is the intervention, sham or control.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Opposite the 17 Shahrivar Hospital, ShahidSiadati Streethid, Namjoo Street
City
Rasht
Province
Guilan
Postal code
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Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.GUMS.REC.1398.072

Health conditions studied

1

Description of health condition studied
Physiological and behavioral indices of pain, duration of crying
ICD-10 code
Z00.12
ICD-10 code description
Encounter for routine child health examination

Primary outcomes

1

Description

Pain level in the FLACC behavioral checklist

Timepoint

At first,the level of infant's pain in three groups of intervention, sham and control for one minute before massage is measured and recorded.Then massage performed for each group(Massage at the relevant points in the intervention group and neutral massage in the sham group).After this stage, the pain level will be measured and recorded for one minute in each of the three intervention, sham and control groups before the painful stimulus (after massage) and during painful stimulation (vaccine injection).

Method of measurement

Using the FLACC scale (Face, Leg, Activity, Cry, Consolability), an appropriate tool for assessing pain-related behaviors in children ages 2 months to 7 years.This scale has 5 sections and examines the severity of pain through face reactions, leg positions,activity , crying and consolability.Each of these sections gives a score of 0 to 2, which ultimately brings together scores. Based on the overall score, zero score means no pain and 10 means the sharpest pain level.The overall score is divided into three levels: score 0 to 3 represents a reduction in pain, 4 to 7 represents moderate pain, and 7 to 10 means severe pain.

Secondary outcomes

1

Description

Mean score of physiological indices(Heart rate, Arterial blood oxygen saturation), average crying time

Timepoint

At first, the physiological indices of infants in three groups of intervention, sham and control by pulse oximeter are measured and recorded for one minute before massage.Massage will then be performed for each group (massage at the relevant points in the intervention group and neutral area massage in the sham group).After this stage, physiological indices for one minute will be measured and recorded in each of the three intervention, sham and control groups before the painful stimulus (after massage) and during the acute stimulus (vaccine injection) are performed.

Method of measurement

To measure physiological indices (arterial blood oxygen saturation, heart rate), a child finger pulse oximeter ,The brand Zyklusmed, will be used with China's CMS 50 QB code.The Galaxy J7 Pro SM-J730F stopwatch will be used to measure infant crying time.

Intervention groups

1

Description

Intervention group: The intervention will be carried out by the researcher who holds the reflexology certificate.The intervention method will be used by the researcher to wash his hands and, to reduce the friction, it will be impregnated with a neutral, non-curative baby oil.This oil is produced by Firouz's Health Group, which has the ability to soothe and maintain the skin's moisture.After warming the hands, each leg will undergo a general massage for warming for one minute.Then, while keeping the researcher with his left hand, holding his infant's leg, with his right finger, he will massage The area of the thighs on the foot of each foot for 15 minutes (a total of 30 minutes per infant).

Category

Other

2

Description

Intervention group: The intervention method will be used by the researcher to wash his hands and, to reduce the friction, it will be impregnated with a neutral, non-curative baby oil.This oil is produced by Firouz's Health Group, which has the ability to soothe and maintain the skin's moisture.After warming the hands, each leg will undergo a general massage for warming for one minute.Then, the researcher will massage the neutral point (foot area under the ankle) on each foot for 15 minutes (a total of 30 minutes per infant).

Category

Placebo

3

Description

Control group: In the control group, vaccination will be performed according to the usual routine of the center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health center number 7 Rasht

Full name of responsible person

Parichehr Shahroudi Tamrin

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
privacy of the data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The research report will be sent to deputy of research and technology of Guilan University of Medical Sciences
When the data will become available and for how long
March 2020
To whom data/document is available
Health Center managers and relevant policymakers
Under which criteria data/document could be used
Descriptive analysis
From where data/document is obtainable
To deputy of research and technology of Guilan University of Medical Sciences
What processes are involved for a request to access data/document
To deputy of research and technology of Guilan University of Medical Sciences
Comments
This is a proposal in from of Master of science in nursing.thank you so much