

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The comparison of the effect of mother milk odor and non nutritive sucking on physiological and behavioral pain responses caused by hepatitis B vaccination in term infants.

Protocol summary

Summary

After birth, infants are exposed to numerous painful measures and there is a talent for getting to the negative effects of pain. To reduce pain, Use of non-pharmacological methods of pain control are effective. in this study, The effect of two non-pharmacological pain managements (Non-nutritive sucking and olfactory stimulation with mother milk) is compared. The population of the study, infants born in the ninth day hospital in Torbat heydariye receive the first dose of hepatitis B vaccine, will form with gestational age of 37 to 42 weeks and birth weight of 2500 to 3500 gram and The last time they did not receive pain medication. infants will be selected by convenience sampling. A total of 90 samples were randomly divided into three groups, two groups, the smell of breast milk odor and non nutritive sucking and a control group exposed. in the breast milk odor group, Olfactory stimulation is done from three minutes before to completion of the vaccination. in the non nutritive sucking group, soft and standard Pacifier will be used of three minutes before to completion of the vaccination. In the control group nothing will be done before and after vaccination. Pain physiological responses (heart rate, respiratory rate and oxygen saturation) will be recorded in two stages, before and after the intervention and pain behavioral responses is recorded using standard tools for assessing pain in infants (MBPS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072423323N1**

Registration date: **2015-11-22, 1394/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-22, 1394/09/01

Registrant information

Name

Elaheh Amiri SHadmehri

Name of organization / entity

Gonabab University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Gonabad University of Medical Sciences.

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of mother milk odor and non nutritive sucking on physiological and behavioral pain responses caused by hepatitis B vaccination in term infants.

Public title

The comparison of the effect of mother milk odor and non nutritive sucking on physiological and behavioral pain responses caused by hepatitis B vaccination in term infants.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: term infants with gestational age 37 to 42 weeks, apgar score 8 and higher than 8 in birth time, do not receive sedation drug from before 48 hours, The absence of congenital malformations. exclusion criteria: Any respiratory and digestive problems appearance during intervention, Discourage parents from participating in research.

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

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

Gonabab University of Medical Sciences

Street address

KHorasan Razavi, Gonabad, Asian roadside, Gonabad
University of Medical Sciences

City

Gonabad

Postal code

9691793718

Approval date

2015-06-24, 1394/04/03

Ethics committee reference number

ir.gmu.rec.1394.22

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

M79.6

ICD-10 code description

pain in limb

Primary outcomes

1

Description

heart rate, percent of oxygen saturation, breathing

Timepoint

Immediately before and after the intervention

Method of measurement

measuring heart rate In beats per minute, measuring oxygen saturation with use of pulse oximeter and respiratory rate in The number of movements of the chest in a minute

2

Description

pain behavioral responses

Timepoint

during vaccination

Method of measurement

infabt pain of assessment tool behavioral responses

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

in the mother milk odor group, 2ml from the infant 's mother milk, has been prepared in the morning before the start of nutrition.poured on a gas is left at a distance of 3 cm from his nose. olfactory stimulation begins from 3 minuts before vaccination and continue to its completion.physiological responses are recored before and after the intervention and behavioral responses will be grade from the beginning to the end of the procedur.

Category

Prevention

2

Description

in the non nutritive sucking group, a kind of latex, soft and standard pacifier is used for each infant and with a soft pressure is kept in the mouth of the baby.This action

started from 3 minute before vaccination and will continue until its completion. .physiological responses are recored before and after the intervention and behavioral responses will be grade from the beginning to the end of the procedur.

Category

Treatment - Drugs

3**Description**

In the control group, no intervention is done. Physiological responses is recorded before vaccination and after its completion and Behavioral responses, will be graded from the beginning to the end of the procedure.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

ninth day hospital city of Torbat Heydariye

Full name of responsible person

Elaheh Amiri SHadmehri, Graduate Student in Nursing Education, Nursing chidren

Street address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Mohammadpour Ali, Research and Tecnology Department of Gonabad University of Medical Sciences, Pr

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Gonabad, Asian roadside, Gonabad University of Medical Science

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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

Gonabad 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**

ninth day hospital

Full name of responsible person

Elaheh Amiri SHadmehri

Position

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Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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