

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect Cooling Gel Pad Versus Non-Nutritive Sucking on the pain caused by the injection of hepatitis vaccine in newborns

Protocol summary

Study aim

Comparison of the effect of Cooling Gel Pad Versus Non-Nutritive Sucking on Pain during Hepatitis B Vaccination in Term born Infants

Design

Clinical trial with control group Neonets are selected by convenience sampling and divided into three groups. In the first group we laid 90 second Cooling Gel Pad on selected tissue region then injection performed in same cooled region. In the second group, sucking was done for 2 minutes before and during the injection of the vaccine. Control group did not receive any intervention during vaccine injection.

Settings and conduct

Pain duration was assessed during 2 minute after intramuscular injection regularly every 30 second by researcher under NIPS pain scale. Cry time was recorded during 2 minutes after needle penetration by stopwatch

Participants/Inclusion and exclusion criteria

Healthy babies, term, normal birth weight, APGAR 7 and more, at least 2 hours, and at most 24 hours since birth.

Intervention groups

Cooling Gel Pad, Non-Nutritive Sucking and without intervention groups

Main outcome variables

_Pain relief _Reduction of the duration of crying

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141004019399N2**

Registration date: **2018-09-02, 1397/06/11**

Registration timing: **retrospective**

Last update: **2018-09-02, 1397/06/11**

Update count: **0**

Registration date

2018-09-02, 1397/06/11

Registrant information

Name

Hadi Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4335 9253

Email address

najafih901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-20, 1393/03/30

Expected recruitment end date

2014-08-20, 1393/05/29

Actual recruitment start date

2014-07-12, 1393/04/21

Actual recruitment end date

2014-09-21, 1393/06/30

Trial completion date

empty

Scientific title

Comparison of the effect Cooling Gel Pad Versus Non-Nutritive Sucking on the pain caused by the injection of hepatitis vaccine in newborns

Public title

Comparison of topical cryotherapy and Non-Nutritive Sucking on the pain caused by vaccine injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parent's informed consent and cooperation fetal gestational age 42-37 weeks 4000-2500 gm birth weight At least the last two hours of birth Within 24 hours of birth is past Body temperature is between 37.2 to 36 At least 30 minutes have passed since the last feeding a baby Babies do not have addicted mothers

Exclusion criteria:

No desire to cooperate and participate parents Mothers who are taking anti-epileptic drugs and anti convulsants The baby cried, severe restlessness Poor sucking and non- effective infant

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **113**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

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 Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology University, Building Qureshi, Daneshgah St, Mashhad

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Razavi Khorasan

Postal code

91775-1365

Approval date

2014-03-15, 1392/12/24

Ethics committee reference number

IR.MUMS.REC.1392.903

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

M79.60

ICD-10 code description

Pain in limb, unspecified

Primary outcomes**1****Description**

Intensity of pain

Timepoint

Every 30 seconds to 2 minutes after the needle is inserted

Method of measurement

neonatal infant pain scale(NIPS)

Secondary outcomes**1****Description**

Duration of crying

Timepoint

Cry time was recorded during 2 minutes after needle penetration by stopwatch.

Method of measurement

by Stopwatch

Intervention groups**1****Description**

Intervention group1:The first group we laid 90 second Cooling Gel Pad on selected tissue region then injection performed in same cooled region.

Category

Rehabilitation

2**Description**

Intervention group2: The second group, sucking was done for 2 minutes before and during the injection of the vaccine.

Category

Rehabilitation

3**Description**

Control group : The control group did not receive any intervention during vaccine injection.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational, Research and Treatment Center

Full name of responsible person

Soheila karbandi

Street address

Daneshgah St, Ibn-e Sina St, School of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hadi Najafi

Position

MSc in Neonatal Intensive Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Position

MSc Nursing Education, Faculty member of School of Nursing and Midwifery, Mashhad

Latest degree

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Latest degree

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Web page address

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

Babies are admitted to the mother's case and there is no comprehensive information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available