

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Pain intensity analysis in different groups who receiving Glucose, Sacarose and control following vaccination against hepatitis B in newborns of Shahid Mostafa Khomainsi hospital of Ilam

Protocol summary

Summary

This is double-blinded clinical trial that will be performing in shahid Mustafa Khomeini hospital of ilam city. The aim of study is examination the effect of Glucose and sacarose on pain due to newborns vaccination in 90 newborn. Inclusion criteria: 1-dryness of newborn diapers. 2-no disease or surgical procedures. 3-full term newborn. 4-no analgesics usage for newborn. 5-NPO at least 30 min before injection of vaccine. Exclusion criteria: 1- presence of abnormality. 2- pre-term newborns. The samples will be select by convenience method and assigned in groups of sacarose, Glucose and control randomly. In first mentioned groups researcher give 2cc oral Glucose 25% and sacarose25% through syringe in 30 s then after 2 min, Hepatitis-B vaccine injected and the pain severity measured by NIPS scale during 1-2 min. In control group there is no intervention.Hepatitis-B vaccine injected and the pain severity measured by NIPS scale during 1-2 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304096790N3**
Registration date: **2013-05-22, 1392/03/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-22, 1392/03/01

Registrant information

Name

Zainab Suhrabi

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 1222 7123

Email address

suhrabi-z@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research and technology, Ilam University of Medical Sciences

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain intensity analysis in different groups who receiving Glucose, Sacarose and control following vaccination against hepatitis B in newborns of Shahid Mostafa Khomainsi hospital of Ilam

Public title

Pain intensity analysis in different groups who receiving Glucose, Sacarose and control following vaccination against hepatitis B in newborns of Shahid Mostafa Khomainsi hospital of Ilam

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1-dryness of newborn diapers. 2-no

disease or surgical procedures. 3-full term newborn. 4-no analgesics usage for newborn. 5-NPO at least 30 min before injection of vaccine. Exclusion criteria: 1- presence of abnormality. 2- pre-term newborns.

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences

Street address

Banganjab- Pajohesh Blvd.

City

Ilam

Postal code

Approval date

2012-01-18, 1390/10/28

Ethics committee reference number

999/52/22

Health conditions studied

1

Description of health condition studied

Vaccination pain

ICD-10 code

Z51.4

ICD-10 code description

Preparatory care for subsequent treatment, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

During vaccine injection

Method of measurement

NIPS criteria

Secondary outcomes

empty

Intervention groups

1

Description

In sacarose group researcher give 2cc oral sacarose25% through syringe in 30 s then after 2 min, Hepatitis-B vaccine injected and the pain severity measured by NIPS scale during 1-2 min

Category

Prevention

2

Description

In Glucose group researcher give 2cc oral Glucose 25% through syringe in 30 s then after 2 min, Hepatitis-B vaccine injected and the pain severity measured by NIPS scale during 1-2 min

Category

Prevention

3

Description

In control group there is no intervention.Hepatitis-B vaccine injected and the pain severity measured by NIPS scale during 1-2 min

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mustafa Khomeini hospital

Full name of responsible person

Zainab Suhrabi

Street address

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr. Morovat Taheri kalani

Street address

Banganjab-Deputy of research and technology

City

Ilam

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Zainab suhrabi

Position

Faculty member- lecturer

Other areas of specialty/work

Street address

Banganjab- Pajoheh Blvd

City

Ilam

Postal code

Phone

+98 84 1222 7123

Fax

Email

suhrabi2007@yahoo.comsuhrabi-z@medilam.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Zainab suhrabi

Position

MS

Other areas of specialty/work

Street address

Banganjab- pajohesh Blvd

City

Ilam

Postal code

Phone

+98 84 1222 7123

Fax

Email

suhrabi2007@yahoo.comsuhrabi-z@medilam.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ilam University Of Medical Sciences

Full name of responsible person

Zainab Suhrabi

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Faculty member- lecturer

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Street address

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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