

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of facilitated tucking on heel stick pain in preterm infants

Protocol summary

Summary

Objectives: The effect of facilitated tucking on heel stick pain in preterm infants. **Design:** This is a cross over clinical trial. **Setting and conduct:** In this study 40 newborns hospitalized in neonatal intensive care unit in Amir Kabir hospital of Arak will be selected purposively and allocated randomly into two groups. **Inclusion criteria:** Gestational Age between 32-36 weeks; Weight more than 1200 grams; Body temperature between 36-37.2 °C; Absence of hypoglycemia or hyperglycemia; Not taking analgesics or anti-epileptic drugs 4 hours before intervention; Not having congenital malformations, seizure, and intracranial hemorrhage; Not performing other painful procedures at least half an hour before intervention; No need for mechanical ventilation. **Exclusion criteria:** More than one try for blood sampling; Parental refusal of participating in the study. **Intervention:** The study will be done in two stages. In the first stage, the two groups will be selected randomly. In group 1, two minutes before blood sampling, the newborn will be assessed by Premature Infant Pain Profile (PIPP). Then the newborn will be put in facilitated tucking position by the nurse, and this will be continued until 3 minutes after blood sampling. Assessment with PIPP will be done again, during and 3 minutes after blood sampling. In group 2, this process will be done but not in facilitated tucking position. In the second stage, blood sampling in group 2 will be done in facilitated tucking position and in group 1 in the routine position. The collected data will be compared in three phases and in two groups. **Main outcome variables:** Newborn pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604041788N16**

Registration date: **2016-09-12, 1395/06/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6150 4212

Email address

borimnej@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Government sources

Expected recruitment start date

2016-03-04, 1394/12/14

Expected recruitment end date

2016-06-03, 1395/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of facilitated tucking on heel stick pain in preterm infants

Public title

The influence of being in facilitated tucking on heel stick pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Gestational Age between 32-36 weeks; Weight more than 1200 grams; Body temperature between 36-37.2 °C; Absence of hypoglycemia or hyperglycemia; Not taking analgesics or anti-epileptic drugs 4 hours before intervention; Not having congenital malformations, seizure, and intracranial hemorrhage; Not performing other painful procedures at least half an hour before intervention; No need for mechanical ventilation
Exclusion criteria: More than one try for blood sampling; Parental refusal of participating in the study

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Randomized blocking method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Postal code

1996713883

Approval date

2016-01-11, 1394/10/21

Ethics committee reference number

IR.IUMS.REC.1394.9211451203

Health conditions studied

1

Description of health condition studied

Heel pain during blood sampling

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

Pain in infants

Timepoint

Before intervention, During intervention and 3 minutes after intervention

Method of measurement

Premature Infant Pain Profile (PIPP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: two minutes before blood sampling, the newborn will be assessed by Premature Infant Pain Profile (PIPP). Then the newborn will be put in facilitated tucking position by the nurse, and this will be continued until 3 minutes after blood sampling. Assessment with PIPP will be done again, during and 3 minutes after blood sampling. For second time, the blood sampling will be done in routine position and PIPP will be measured before and after that.

Category

Prevention

2

Description

Intervention group 2: at the first time the process will be done in routine position and Premature Infant Pain Profile (PIPP) will be measured before and after the procedure. In the second time, two minutes before blood sampling, the newborn will be assessed by PIPP. Then the newborn will be put in facilitated tucking position by the nurse, and this will be continued until 3 minutes after blood sampling. Assessment with PIPP will be done again, during and 3 minutes after blood sampling.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Samane Davari Shalamzari

Street address

Amir Kabir Hospital, Parastar sq, Arak, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

Hemmat Highway, Tehran, Iran

City

Tehran

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, Iran 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

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Leily Borimnejad

Position

Phd in Nursing Education

Other areas of specialty/work

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Person responsible for updating data

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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