

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effect of facilitated tucking with the nurse and a simulated hand on physiological pain index during vein puncture on premature infants in neonatal intensive care unit.

Protocol summary

Summary

The goal of the study is to determine the effect of position of fetal in the hand of the nurse or the cloned glove on the physiological indicator during setting the IV for preterm babies with the gestational age of 28- 37 weeks in NICU. The babies are chosen according to the inclusion criteria and are randomly put in one of the three groups of intervention with the nurse's hand, Intervention with the cloned hand or the control group. There are 33 samples in each group. In the population questionnaire for each baby these factors are determined: gestational age, gender, Birth weight and body temperature. Thirty minutes after putting the baby in the rest position the responsible nurse checks the heart rate, number of breathes and oxygen saturation. These factors are checked again after inserting cannula and five minutes after fixing the intra venous line. To be more exact, monitor's Trend option can be used. For the intervention group with hands, researcher nurse should wash her hands and put the baby in the fetal position with warm hands by putting one hand on the baby's head and without any pressure with another hand pushing the legs inside of abdomen. In the group with the cloned hand this position is given to the baby with ergonomic gloves of Zaky. In the control group as the routine no pacifying action is done for the baby.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060128205N1**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Zohre Karjoo

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid sadoghi University of Medical Sciences

Expected recruitment start date

2016-06-03, 1395/03/14

Expected recruitment end date

2016-10-05, 1395/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of facilitated tucking with the nurse and a simulated hand on physiological pain index during vein puncture on premature infants in neonatal intensive care unit.

Public title

The effect of fetal positions on pain management in

preterm infants Neonatal Intensive Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: premature baby with gestational age between 28 till 37 weeks; no opioid and pain killing drugs and withdrawal syndrome; no Hypothermia; Hypoglycemia and hyperglycemia; no mechanical ventilation; no surgery; five minutes Apgar score more than seven. Exclusion criteria: All cases are inconsistent with the inclusion criteria

Age

From **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

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

Shahid Sadoughi University of Medical Sciences and Health Services

Street address

central office of university, Bahonar square

City

Yazd

Postal code

8916978477

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.SSU..REC.1394.22

Health conditions studied

1

Description of health condition studied

Comparison effect of facilitated tucking with the nurse and a simulated hand on physiological pain index during vein puncture on premature infants in neonatal intensive care unit.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, moment of intervention, five minute after intervention

Method of measurement

Physiologic indicator

Secondary outcomes

1

Description

Average heart rate

Timepoint

Before intervention, moment of intervention, 5 minute after intervention

Method of measurement

Physiologic indicator

2

Description

The average arterial oxygen saturation

Timepoint

Before intervention, moment of intervention, five minute after intervention

Method of measurement

Physiologic indicator

3

Description

The average number of breathing

Timepoint

Before intervention, moment of intervention, five minute after intervention

Method of measurement

Physiologic indicator

Intervention groups

1

Description

For the intervention group with hands, researcher nurse should wash her hands and put the baby in the fetal position with warm hands by putting one hand on the baby's head and without any pressure with another hand pushing the legs inside of abdomen

Category

Other

2

Description

Zaky gloves used for fetal positions

Category

Other

3

Description

According to the routine will not do nothing to control the pain

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospitl

Full name of responsible person

Scientific Officer

Street address

Amin Hospital

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Scientific Officer

Street address

Shahid Beheshti Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University

Full name of responsible person

Naiire Salmani

Street address

Building number 2, Bahonar square, Shahid Sadoughi University, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University

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

Shahid Sadoughi University

Full name of responsible person

NaiireSalmani

Position

Nursing PhD

Other areas of specialty/work

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Web page address**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*