Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of environmental and behavioral interventions on the pain of preterm neonates candidated for heel blood sampling in the neonatal intensive care unit

Protocol summary

Summary

The aim of this research is to study the effect of environmental and behavioral interventions on the pain of heel blood sampling in preterm infants. Materials and methods: A single-group clinical trial will be conducted. Thirty two infants with gestational age (GA) of 32-37 weeks will be evaluated in this study in both intervention and control stage. In the intervention stage, the effect of interventions such as noise reduction by ear-plugs, light reduction by blindfolds, reduction of nursing manipulation and creation of intrauterine position will be evaluated for neonates in the time period of 30 minutes before taking blood samples until 30 minutes after it. Then, the required information about the pain of newborns will be collected by the questionnaire measure in 5 stages (before interventions, two minutes before the blood sampling, during sampling, five minutes and 30 minutes after the sampling). In the control stage, no behavioral and environmental intervention will be performed, while the required information will be collected similar to the intervention stage. Inclusion criteria include: GA: 32-37 weeks; age below 7 days; giving no oxygen before and during interventions; receiving at least 2 orders of heel stick blood sampling during two continuous days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092024100N1**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

fatemeh baharlooei

Name of organization / entity

isfahan univercity of medical science

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Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

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

Study of the effect of environmental and behavioral interventions on the pain of preterm neonates candidated for heel blood sampling in the neonatal intensive care unit

Public title

The effects of developmental care on the pain that preterm infants suffer during heel blood sampling in neonatal intensive care unit

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria include: gestational age between 32-37 weeks; age below 7 days; hospitalized in neonatal intensive care unit; giving no oxygen before and during interventions; full consciousness; receiving at least 2 orders of heel blood sampling in two continuous days; not receiving anticonvulsants and anesthetic drugs; lack of diseases such as congenital defects, neurological disorders, bleeding into the ventricles of the brain, and seizure. Exclusion criteria include: Cancellation of participation in research by newborn parents; the need for oxygen therapy in children for any reason before and during the intervention.
Age
From **1 day** old to **7 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University Of Medical Science
Street address
Isfahan University Of Medical Science, Azadi square, Isfahan
City
Isfahan
Postal code
Approval date
2014-11-22, 1393/09/01
Ethics committee reference number
393862

Health conditions studied

1

Description of health condition studied
Preterm Neonate
ICD-10 code
xvi
ICD-10 code description
Certain conditions originating in the perinatal period

Primary outcomes

1

Description
The pain of heel blood sampling
Timepoint
Before intervention, two minutes before heel blood sampling, during heel blood sampling, five minutes after heel blood sampling and 30 minutes after heel blood sampling
Method of measurement
Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention stage, the effect of interventions such as noise reduction by ear-plugs, light reduction by blindfold, reduction of nursing manipulation and creation of intrauterine position will be measured for neonates in the time period of 30 minutes before taking blood samples until 30 minutes after it. In the control stage, no behavioral and environmental intervention will be performed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Fatemeh Baharlooei
Street address
Shahid Beheshti Hospital, Felezi Bridge, Hakim Nezami Avenue,
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan university of medical science
Full name of responsible person
Dr.taleghani
Street address
Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan university of medical science
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
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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