

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm infants candidate for intravenous catheterization in neonatal intensive care units

Protocol summary

Summary

41 preterm infants whose parents agreed with their participation in the present study, were selected. The infants were randomly assigned into two experimental and control groups. In the experimental group, demographic, basic and physiological information questionnaire was completed with NIPS & EDIN Scale before implementing any intervention. Then, environmental and behavioral interventions such as closing the infants' eyes to reduce the light using eye pad, closing the infants' ears to reduce auditory simulations using ear plugs and placing the baby in an embryonic state to reduce environmental simulations using the nests prepared by the researcher, were implemented by researcher. 30 minutes after intervention, while the intervention was going on, intravenous catheter placement was performed by a qualified nurse. At the same time, a graduate student who knew how to fill the measuring tools and had at least one year working experience in the neonatal ward, filled the related checklist at the times of 2 minutes before, during and 5 minutes after intravenous catheter placement. Then, 30 minutes after intravenous catheter placement, while the intervention was going on, the physiologic information form and related checklists were filled again and the infant was removed from the study after an hour. No environmental and behavioral interventions were implemented on the infants in the control group, but, like the first time, all the stages of collecting information and filling the checklists were performed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011231892N1**

Registration date: **2017-09-24, 1396/07/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-24, 1396/07/02

Registrant information

Name

Anahita Masoumpoor

Name of organization / entity

Martyr Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8865 5366

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masoumpoor.a@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm

infants candidate for intravenous catheterization in neonatal intensive care units

Public title

The effect of environmental and behavioral interventions on physiological and behavioral responses of preterm infants candidate for intravenous catheterization in neonatal intensive care units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria; gestational age of 30-37 weeks; admission to neonatal intensive care unit; requiring administration of intravenous fluids and catheter; constant positive airways pressure (N-CPAP); no use of sedatives, anticonvulsants, or anesthetics; no comorbidities such as congenital abnormalities, neurological problems, or cerebral intra-ventricular hemorrhage and seizures and; fully conscious infant; Exclusion criteria; parents withdrawing participation of their infant; failure to insert intravenous catheter in two attempts; critical illness of infant in the process of its disease interfering with interventions; lack of response to N-CPAP .

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: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Using colored beads

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Martyr Beheshti University of Medical Sciences

Street address

Tehran, Vali Asr intersection of prayer, the Heart Hospital Rajai martyr, martyr Beheshti University of Medical Sciences

City

Tehran

Postal code

1985717443

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.587

Health conditions studied

1

Description of health condition studied

Premature infants

ICD-10 code

p07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.

Primary outcomes

1

Description

physiological responses

Timepoint

2 minutes before venipuncture, during venipuncture, 5 and 30 minutes after venipuncture

Method of measurement

Pulse monitoring, observation

Secondary outcomes

1

Description

Behavioral responses

Timepoint

2 minutes before venipuncture, during catheter insertion, 5 and 30 minutes after venipuncture

Method of measurement

NIPS scale & EDIN scale

Intervention groups

1

Description

The intervention implemented in the experimental group: "environmental and behavioral interventions such as closing the infants' eyes to reduce the light using eye pad, closing the infants' ears to reduce auditory simulations using ear plugs and placing the baby in an embryonic state to reduce environmental simulations using the nests prepared by the researcher, are implemented by researcher. 30 minutes after intervention, while the intervention is going on, intravenous catheter placement is performed by a

qualified nurse. At the same time, a nurse who knows how to fill out the measuring tools and has at least one year working experience in the neonatal ward, fills out the related checklist at the time of 2 minutes before, during and 5 minutes after intravenous catheter placement. Then, 30 minutes after intravenous catheter placement, while the intervention is going on, the physiologic information form and related checklists are filled out again and the infant is removed from the study after an hour."

Category

Behavior

2**Description**

The intervention implemented in the control group: "no environmental and behavioral interventions, except for routine cares, are implemented on the infants in the control group, but all the stages of collecting information and filling out the checklists are done and recorded like the first time."

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospital Al zahra Isfahan

Full name of responsible person

Shohreh Taheri Karchegani , Nursing Graduate
Student newborns

Street address

Hospital Alzahra, Sofe Blvd, Isfahan

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Martyr Beheshti University of Medical Sciences

Full name of responsible person

Shohreh Taheri Karchegani

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School of Nursing and Midwifer, The intersection of
prayer, Valiasr Street, The martyr Rajai Hospital
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

Martyr Beheshti 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**

Martyr Beheshti University of Medical Sciences

Full name of responsible person

Shohreh Taheri Karchegani

Position

Master's student nursing specialist neonates

Other areas of specialty/work**Street address**

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Position

Phd

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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