

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparsion of two methods nest and handpillow on physiologic variables premature infants hospitalized in neonatal intensive care unit of Hazrat Zeinab hospital, Shiraz

Protocol summary

Summary

The main objective of the study the determine the avoidable cause physiological disorders in premature infants hospitalized in neonatal intensive care unit intervention and control groups. Informed consent was signed by the parents that the baby is placed in one of two study groups and parents do not know their child groups. So this study is a single blind study. Inclusion criteria for the study included premature infants weighing less than 2500 grams and with gestational age 24-36 weeks, premature infants birth to age 2 to 3 days, the first and fifth minutes APGAR between 7-10, infants with doctor confirmed the status register, parental consent for children to participate in the study, no history of addiction and/or taking sedative drugs and hypnotics in infants during the intervention. Exclusion criteria: unwillingness of parents to continue cooperation during the study, creating any problem. 70 infants by creating random numbers with the method of block permutation divided into two groups, control and intervention. In intervention group we use handpillow for infants and we use nest for control group. In this study the main outcome variable, physiological variables contains heart rate, respiratory rate and O2 saturation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062628636N1**

Registration date: **2017-05-20, 1396/02/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Atila Erami

Name of organization / entity

Shiraz university

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of two methods nest and handpillow on physiologic variables premature infants hospitalized in neonatal intensive care unit of Hazrat Zeinab hospital, Shiraz

Public title

Pillows effect on infant development

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-preterm infants weighing less than

1500 grams and gestetional age 24-36 weeks. 2-preterm infants with posnatal age 2-3 days. 3-the first and fifth minute apgar 7-10. 4- infants with physician stability 5- parental consent to participate in the study. 6-no history of drug abuse and use of tranquilizers and sleeping mom. 7-do not use hypnotic and sedative drugs to the infant during intervention. Exclusion criteria: 1-unwillingness of parents to continue working during study. 2-report any problems during the study.

Age

To **29 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz,zand street,across the street palestinian-
building of the central University of Medical
Scinces,Shiraz

City

shiraz

Postal code

7134814336

Approval date

2016-10-09, 1395/07/18

Ethics committee reference number

95-01-08-11735

Health conditions studied

1

Description of health condition studied

Developmental care

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Respiratory Rate in intervention group

Timepoint

Intervention time

Method of measurement

Pulse oximetry

2

Description

Heart Rate in intervention group

Timepoint

before and in intenvention time

Method of measurement

Pulse oximetry

3

Description

O2 Saturationin intervention group

Timepoint

Intervention time

Method of measurement

Pulse oximetry

4

Description

Respiratory Rate in control group

Timepoint

before and in intenvention time

Method of measurement

pulse oximetry

5

Description

Heart Rate in control group

Timepoint

before and in intenvention time

Method of measurement

pulse oximetry

6

Description

O2 Saturationin control group

Timepoint

before and in intenvention time

Method of measurement

pulse oximetry

Secondary outcomes

1

Description

Regulate Body Temperature in control group

Timepoint

intervention time

Method of measurement

termometer

2

Description

Regulate Body Temperature in intrrvention group

Timepoint

Intervention time

Method of measurement

Termometer

Intervention groups

1

Description

Hand pillow an optimal intervention group is a means to position the babies particularly premature infants who can not maintain their status and also to increase the stability of relationship and attachment between mother and babies and stability of physiological parameter

Category

Prevention

2

Description

Nest in control group is a means to stabilize the situation they approached the baby curved shoulders ,wrist movements to facilitate the mid line and motor and postural rigidity suspension arms and legs to reduce and prevent newborns from sudden moves and uncomfortable

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab hospital

Full name of responsible person

Atila Erami

Street address

Hazrat Zeinab hospital, Defa Moghadas square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Ave.

City

Shiraz

Grant name

95-01-08-11735

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz university of Medical Sciences

Full name of responsible person

Mitra Edraki

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Master of nursing

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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