

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of training attachment behavior to mother on physiological status and response to behavior preterm infants in the neonatal intensive care unit depend to shiraz university of medical sciences in 2013

Protocol summary

Summary

1) Objectives: evaluation the effect of training attachment behavior to mother on physiological status and response to behavior preterm infants in the neonatal intensive care unit. 2) Design: single-blind randomized clinical trial. 3) Setting and conduct: 64 premature infants who are eligible for the study are divided by the randomized sampling allocation into two experimental and control groups. The infants in the experimental group training attachment behavior to mother using the infant and the infants in the control group the method of training attachment by nurses unit. Body temperature, heart rate, respiratory rate, and blood oxygen saturation are measured. Physiological parameters to three times are measured: the first time half an hour before the exit to bed, 2: during intervention 3: half hour after entering to bed. Response behavior 2 hours before exit and 2 hours after entrance are checked by a nurse who is kept uninformed about the study and its assumptions. To record the behavioral responses, the infant's face is captured in close-up during the after intervention and before intervention. The films are interpreted by an observer without knowledge of the intervention type. Finally, the changes in the physiological and behavioral parameters are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070818406N2**

Registration date: **2014-08-31, 1393/06/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-31, 1393/06/09

Registrant information

Name

Sahra Zende Zaban

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 4525 2851

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of training attachment behavior to mother on physiological status and response to behavior preterm infants in the neonatal intensive care unit depend to shiraz university of medical sciences in 2013

Public title

Evaluation the effect of training attachment behavior to mother on physiological status and response to behavior preterm infants in the neonatal intensive care unit depend to shiraz university of medical sciences in 2013

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: gestational age of 32–36 weeks; postnatal age of 7–30 days; weight 1500–2500 grams; not using sedatives and short- or long-acting skeletal muscle relaxant drugs; not having substance abuse issues and no sedative drug use by the mother; no major congenital, chromosomal or neurological abnormalities; stability of physiological parameters in the infant; ability for oral breast feeding, and keep in incubator. Exclusion criteria: need to ventilator in the infant; need to oxygen therapy; inability for oral breast feeding; using sedatives and short- or long-acting skeletal muscle relaxant drugs;; parents' unwillingness to continue cooperating in research.

Age
From **1 day** old to **1 month** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

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
Ethics Committee of Shiraz University of Medical Sciences

Street address
zand

City
shiraz

Postal code

Approval date
2014-06-30, 1393/04/09

Ethics committee reference number

93-7057

Health conditions studied

1

Description of health condition studied

Preterm infants

ICD-10 code

P07.3

ICD-10 code description

Prematurity NOS

Primary outcomes

1

Description

Temperature

Timepoint

First time half an hour before the exit from the bed, second time during intervention and third time half hour after entering to the bed

Method of measurement

Thermometer

2

Description

Heart rate

Timepoint

First time half an hour before the exit from the bed, second time during intervention and third time half hour after entering to the bed

Method of measurement

Pulse oximetry

3

Description

Blood oxygen saturation

Timepoint

First time half an hour before the exit from the bed, second time during intervention and third time half hour after entering to the bed

Method of measurement

Pulse oximetry

4

Description

Respiration rate

Timepoint

First time half an hour before the exit from the bed, second time during intervention and third time half hour after entering to the bed

Method of measurement

Observation

5

Description

Behavioral responses
Timepoint
First time 2 hours before exit and second time 2 hours after entering to the bed(incubator)
Method of measurement
Video camera

Secondary outcomes

empty

Intervention groups

1

Description

For the infants in the experimental group, training attachment behavior to mothers' of the infants are performed by the researcher. Body temperature, heart rate, respiratory rate, and blood oxygen saturation are measured. Physiological parameters to three times are measured: the first time half an hour before the exit to bed, 2: during intervention 3: half hour after entering to bed. Response behavior 2 hours before exit and 2 hours after enter checked by a nurse who is kept uninformed about the study and its assumptions. To record the behavioral responses, the infant's face is captured in close-up during the after intervention and before intervention. The films are interpreted by an observer without knowledge of the intervention type. Finally, the changes in the physiological and behavioral parameters of the

Category

Prevention

2

Description

In the control group the method of training attachment are performed by nurses. Body temperature, heart rate, respiratory rate, and blood oxygen saturation are measured. Physiological parameters to three times are measured: the first time half an hour before the exit to bed, 2: during intervention 3: half hour after entering to bed. Response behavior 2 hours before exit and 2 hours after enter checked by a nurse who is kept uninformed about the study and its assumptions. To record the behavioral responses, the infant's face is captured in close-up during the after intervention and before intervention. The films are interpreted by an observer without knowledge of the intervention type. Finally, the changes in the physiological and behavioral parameters of the

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital
Full name of responsible person
Sahra Zندهzaban
Street address
Hafez hospital, Abiverdi Street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

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, 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 - Hazrat-e-Fatemeh Nursing and Midwifery Faculty

Full name of responsible person

Sahra Zنده Zaban

Position

Neonatal Intensive Care Nursing Master of Science Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Mitra Edraki
Position
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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work
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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