

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of enviromental and behaivire intervention on the sleep cycle of newborne hospitalized

Protocol summary

Study aim

A comparison between effect of environmental and behavioral Intervention on sleep cycle of infants in NICU

Design

In this prospective crossover clinical trial, 40 preterm infants with fetal age of 32 to 36 weeks Infants randomly divide into two groups include environmental-behavioral intervention and behavioral -environmental intervention. Then each course of study includes: control course, first intervention and second intervention have held in 2 hours.

Settings and conduct

this study is prospective crossover clinical trial. Sampling was from July 22nd, 2016 to December 21st, 2016 in Alzahra Institute dependent on Isfahan University of Medical Science.

Participants/Inclusion and exclusion criteria

Fetal age 32 to 24 weeks , neonatal age of 1-20 days, self-breathing without support, no congenital defect and no abnormal neurologic finding , no usage of addictive drugs by mother in pregnancy, no sedative therapy in last 24 hours, impossible to do kangaroo mother care or limitation to use it or mother unwilling or absence, no diarrhea, no infant rehospitalization, APGAR>4 , every 2 hours feeding

Intervention groups

Environmental intervention : in Environmental intervention course, we decrease the light and turn off extra lamps and noises reduce by inserting earplugs in infant's ears. behavioral intervention: In behavioral intervention course, we make a fetal position for infants by ward tools and Avoiding any not necessary manipulation.

Main outcome variables

three different courses has significant differences in time of sleep.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037282N2**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **retrospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

samira karami

Name of organization / entity

Isfahan University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5224 4786

Email address

samirakarami60@gmail.com

Recruitment status

Recruitment complete

Funding source

institution

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-02-22, 1395/12/04

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2017-02-22, 1395/12/04

Trial completion date

empty

Scientific title

Effects of enviromental and behaivire intervention on the sleep cycle of newborne hospitalized

Public title

Effects of enviromental and behaivire intervention on the sleep cycle of newborne hospitalized

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Fetal age 32 to 24 weeks base on mother LMP or ultrasound, self-breathing without support no congenital defect and no abnormal neurologic finding include intraventricular hemorrhage (more than grade 2) no sedative therapy in last 24 hours no usage of addictive drugs by mother in pregnancy,, impossible to use it or mother unwilling or absence, no diarrhea, no infant rehospitalization, APGAR>4 every 2 hours feeding neonatal age of 1-20 days

Exclusion criteria:

necessary need to do special intervention during study parents refuse to continue the study.

Age

From **1 day** old to **20 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Isfahan University of Medical Sciences

Street address

Faculty of Nursing &Midwifery Hezarjereeb Avenue,

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۵

Approval date

2017-01-16, 1395/10/27

Ethics committee reference number

IR.MUI.REC.1395.3.953

Health conditions studied

1

Description of health condition studied

comparison between effect of environmental and behavioral Intervention on sleep cycle of infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

comparison sleep cycle of infants

Timepoint

6 hours

Method of measurement

Pertchl Scale

Secondary outcomes

empty

Intervention groups

1

Description

behavioral intervention course, we made a fetal position for infants by ward tools and Avoiding any not necessary manipulation

Category

Behavior

2

Description

in Environmental intervention course, we decrease the light and turn off extra lamps and noises reduce by inserting earplugs in infant's ears.

Category

Other

3

Description

no interventions

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Rahmani Manesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

395953

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samira karami

Position

Graduate level

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable