

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of artificial night and facilitated tucking position on the physiological parameters in premature infants.

Protocol summary

Study aim

Determination and Evaluation of the Effect of Artificial Night and Facilitated tucking position on Physiological Parameters in Premature Infants

Design

Patients are numbered according to the order of referral. Using a random number table provided by the software, 60 qualified eligible babies are divided into 3 groups. In addition, the investigator himself does not have a randomized list

Settings and conduct

Neonatal Intensive Care Unit of Yazd Social Security Hospital The researcher did not know at the beginning of the sampling the list of samples and their placement in the investigated groups, and the information analyst had no information about them either.

Participants/Inclusion and exclusion criteria

inclusion criteria: Gestational age between 36-32 weeks, respiratory score less than 5, fifth minute apgar scores 7 and more, breastfeeding by gavage method. excluded criteria: Infants of addicted mothers, equal or more than 5 respiratory score, restless babies, fifth minute Apgar scores less than 7, neonates requiring phototherapy, prematurely with other illnesses such as cardiac abnormalities, congenital anomalies, metabolic disease, needy Surgery

Intervention groups

infants in group 1 receive artificial night with facilitated tucking position and in group 2, infants will be placed in artificial night and newborns in group 3 (control group) are in routine care only .

Main outcome variables

Physiological parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171226038086N1**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **retrospective**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Akram Raie ezabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3821 8420

Email address

a.raei@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of artificial night and facilitated tucking position on the physiological parameters in premature infants.

Public title

The effect of artificial night and facilitated tucking position in premature infants.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

GA:32-36W respiratory score<5 apgar score in min 5 >7 breast feeding with gavage

Exclusion criteria:

Respiratory score>5 addict infant mothers restless infants apgar score in min 5 <5 infants needed phototherapy others disease for example congenital heart disease and malformations,metabolic disease, surgical cases

Age

From **1 day** old to **4 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are numbered according to the order of referral. Using a random number table provided by the software, 60 qualified eligible babies are divided into 3 groups. In addition, the investigator himself does not have a randomized list.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

yazd shahid sadoughi university of medical sciences

Street address

shahid bahonar square-central university building

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2017-03-18, 1395/12/28

Ethics committee reference number

ir.ssu.rec.1395.225

Health conditions studied

1

Description of health condition studied

physiological parameters

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

heart rate

Timepoint

before and during intervention

Method of measurement

pulse oximeter

2

Description

respiratory rate

Timepoint

before and during intervention

Method of measurement

pulse oximeter

3

Description

arterial oxygen saturation percent

Timepoint

before and during intervention

Method of measurement

pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(1): Infants who are placed under artificial night and facilitated tucking position. To create an artificial night in the dark period of 19 pm to 7am, a black duplex lining from the four sides placed on incubators, and during the light period, from 7 to 19, the coating is removed on the incubator. To create and maintain facilitated tucking in different positions(prone or siding) is used in soft, medium-soft towels, and the baby is placed while the hands and feet are glued to the body and placed near the face and mouth.

Category

Other

2

Description

Intervention group(2): infants who are under normal position in artificial night conditions

Category

Other

3

Description

Control group: infants who were routinely treated (normal position without artificial night intervention)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Social Security Hospital

Full name of responsible person

Department responsible for science

Street address

Yazd Social Security Hospital

City

yazd

Province

Yazd

Postal code

8944167699

Phone

+98 35 3182 2000

Fax

+98 35 3825 0007

Email

hospital.kargar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

دکتر مسعود میرزایی

Street address

Shahid Bahonar Square - Central University Building

City

yazd

Province

Yazd

Postal code

8916978477

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+98 35 3724 0151

Fax

+98 35 3725 8413

Email

info@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Khadije Dehghani

Position

Master's Degree - Academic

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yazd - Bouali Ave. - Faculty of Nursing and Midwifery

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yazd

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Yazd

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Phone

+98 35 3824 1752

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shadehghani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Khadije Dehghani

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Master's Degree - Academic

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Yazd University of Medical Sciences

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Khadije Dehghani

Position

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Latest degree

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yazd

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Yazd

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

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

Data Dictionary

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