

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Kangaroo care mothers on vital signs and O2 saturation of neonates in NICU of Shaheed Sadooghi Hospital

Protocol summary

Summary

This study will conduct for effects of Kangaroo care mothers on vital signs and O2 saturation in neonates of NICU in Shahid Sadoughi Hospital of Yazd. This randomized clinical trial will be done on 50 hospitalized newborns which have inclusion criteria for study and then divide in two groups (n=25). inclusion criteria are :gestational age>32 weeks;weight >1800gram and without problem in respiratory, cardiovascular and CNS .Intervention group will be given kangaroo mother care in three consequence days one hour in a day .Newborns will be placed vertically between the mothers breasts and supported in bottom with a sling /blinder. Neonates in the control group will be given conventional care in incubator.Both groups will be monitored for temperature,heart rate,respiratory rate, and o2 saturation at 1 hour after care .Two groups will be compared in vital signs and O2 saturation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901223679N1**

Registration date: **2011-10-21, 1390/07/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-21, 1390/07/29

Registrant information

Name

Khadijeh Dehghani

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences,
Yazd,Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

dehghanish@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Kangaroo care mothers on vital signs and O2 saturation of neonates in NICU of Shaheed Sadooghi Hospital

Public title

Effect of Kangaroo care in newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Neonatal age 32 weeks or more;Weight 1800 gr or more;Neonates without problem in respiratory, cardiovascular and CNS Exclusion criteria: Neonates without inclusion criteria; and their parents dont want to participate

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

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

shahid sadoughi University of Medical sciences

Street address

bahonar square in yazd

City

yazd

Postal code

Approval date

2009-05-16, 1388/02/26

Ethics committee reference number

14810/1/17/p

Health conditions studied

1

Description of health condition studied

new born preterm

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

Temperature

Timepoint

before-half an hour after-in finishing one hour

Method of measurement

NICU thermometer

2

Description

respiration

Timepoint

before-half an hour after-in finishing one hour

Method of measurement

monitor in Nicu

3

Description

heart rate

Timepoint

before-half an hour after-in finishing one hour

Method of measurement

monitor in Nicu

4

Description

o2 saturation

Timepoint

before-half an hour after-in finishing one hour

Method of measurement

pulse oximeter in Nicu

Secondary outcomes

empty

Intervention groups

1

Description

Kangoro care is done by mothers for their newborns with researcher,s supervision and support for one hour in a day in three sequence day

Category

N/A

2

Description

control group:neonates in the control group will be given conventional care in incubator.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid sadoughi Hospital,Yazd

Full name of responsible person

Khadijeh Dehghani

Street address

Nursing and Midwifery ,Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Khadije Dehghani

Street address

Shahid Sadoughi University of Medical Sciences,
Nursing and Midwifery College

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Sadoughi 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**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Khadije Dehghani

Position

Ms

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

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Person responsible for scientific inquiries

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Full name of responsible person

Khadije Dehghani

Position

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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