

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effects of Kangaroo care on Delirium in Neonates under Non-Invasive mechanical Ventilation

Protocol summary

Study aim

Determining the effect of kangaroo care on delirium in neonates under non-invasive mechanical ventilation

Design

Two arm parallel group randomised trial, with total sample size of 50 infants.

Settings and conduct

The neonatal intensive care units of the three hospitals of the Children's Medical Center, Bahrami and Shariati will be the place of study. Infants are randomly assigned to the intervention and control groups based on the start date of non-invasive mechanical ventilation. Evaluation of both intervention and control groups for delirium during the study period is performed using the Cornell Assessment of Pediatric Delirium (CAPD) at 7 p.m. by researcher or caregiver based on documentation and observations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being under non-invasive mechanical ventilation The corrected age of the infant at the time of enrollment (initiation of non-invasive mechanical ventilation) should be 35 weeks gestational age (after fertilization) Not being treated with sedatives and anticonvulsants Exclusion criteria: Convulsion and followed that taking anticonvulsants as well as starting sedatives Exposure to non-invasive mechanical ventilation for less than 72 hours Dissatisfaction of the neonate guardian to enter the study Initiation of invasive mechanical ventilation

Intervention groups

Kangaroo care by skin-to-skin contact between mother and infant (at least 30 minutes a day) is the intervention of this study. The study outcome will then be compared with the control group, who received routine care.

Main outcome variables

Score of Cornell Assessment of Pediatric Delirium (CAPD) questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201130049544N1**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Nasim Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6617 9674

Email address

nmirzaeis@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of Kangaroo care on Delirium in Neonates under Non-Invasive mechanical Ventilation

Public title

Investigating the effects of Kangaroo care on Delirium in Neonates under Non-Invasive mechanical Ventilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being under non-invasive mechanical ventilation The corrected age of the neonate at the time of enrollment (initiation of non-invasive mechanical ventilation) should be 35 weeks gestational age (after fertilization) Not being treated with sedatives and anticonvulsants

Exclusion criteria:

convulsion and followed that taking anticonvulsants as well as starting sedatives Exposure to non-invasive mechanical ventilation for less than 72 hours Dissatisfaction and unwillingness of the neonate guardian to enter the study Initiation of invasive mechanical ventilation

Age

To 28 days 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

After entering the study, the samples are assigned to the intervention and control groups based on the start date of non-invasive mechanical ventilation. In this case, if the sample is included in the study on the odd date, it is placed in the intervention group, and if it is included in the study on the even date, it is placed in the control group. If several samples meet the entry requirements on a date, they will be entered into each intervention or control group based on a lottery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the samples are randomly assigned to two groups of intervention and control. The intervention group will receive kangaroo care intervention (for at least 30 minutes a day) based on the study protocol and will eventually be compared to the control group that received routine care.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, School of Nursing, Midwifery and Rehabilitation, Tehran University of

Street address

Unit. 5, No 52, Toos St, Ghasredasht St, Azarbaijan Ave, Jomhouri Squ

City

Tehran

Province

Tehran

Postal code

1345967880

Approval date

2021-01-18, 1399/10/29

Ethics committee reference number

IR.TUMS.FNM.REC.1399.181

Health conditions studied

1

Description of health condition studied

delirium

ICD-10 code

F06.8

ICD-10 code description

Other specified mental disorders due to known physiological condition

Primary outcomes

1

Description

Score of Cornell Assessment of Pediatric Delirium (CAPD) questionnaire

Timepoint

Evaluation of both intervention and control groups for delirium during the study period is performed using the Cornell Assessment of Pediatric Delirium (CAPD) at 7 p.m. daily by researcher or caregiver based on documentation and observations.

Method of measurement

Cornell Assessment of Pediatric Delirium (CAPD) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is performed on neonates who have reached at least 35 weeks of gestation when

non-invasive mechanical ventilation begins. If the baby is born full-time, the maximum time he/she can enter the study is up to 28 days after birth (end of the neonatal period), and if the baby is born pre-term, his/her corrected age is (41 weeks after fertilization) is considered as the maximum time allowed to enter the study. Intervention in the present study, kangaroo care will be in the form of skin-to-skin contact between mother and baby. The minimum duration of skin-to-skin contact is 30 minutes (24 hours a day), which can be intermittent or continuous. The study outcome will then be compared with the control group, who received routine care.

Category

Behavior

2

Description

Control group: The control group in this study will receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Nasim Mirzaei Salout

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2

Recruitment center

Name of recruitment center

Children's Medical Center hospital

Full name of responsible person

Nasim Mirzaei Salout

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3

Recruitment center

Name of recruitment center

Bahrami Children Hospital

Full name of responsible person

Nasim Mirzaei Salout

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehrnaz Geranmay

Street address

Unit. 5, No 52, Toos St, Ghasredasht St, Azarbaijan Ave, Jomhouri Squ

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Nasim Mirzaei Salout

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nasim Mirzaei Salout

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nasim Mirzaei Salout

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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City

Tehran

Province

Tehran

Postal code**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