

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the first skin contact father with their preterm infants admitted to Neonatal Intensive Care Unit (NICU) ward

Protocol summary

Study aim

Determining the effect of first skin contact between fathers and premature infants admitted to neonatal intensive care unit on their anxiety

Design

At first, 72 eligible fathers of neonates were selected and randomly divided into intervention and control groups (n = 36). It was measured and assessed with previous anxiety levels.

Settings and conduct

Selection of fathers with infants admitted to the NICU based on inclusion criteria, explaining the study description and conditions for all individuals and receiving written consent to attend the study, assessing the anxiety of fathers before the intervention using the Spielberger questionnaire, then selecting The two groups were randomized and skin-to-skin contact was performed for the intervention group in a separate room by the trained nurse controlling the physiological stability of the infant and the usual meeting conditions. for the control group and re-examining the fathers' anxiety immediately after.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Calendar age of baby (between 2 to 5 days) 2. The baby with physiological stability conditions 3. Fetal age under 37 weeks 4. Absence of nicotine or caffeine by the father one hour before the start of the study Exclusion criteria 1. Infant receiving oxygen or respiratory distress 2. The father of a drug user 3. drug-using mothers 4. Infants with congenital disease 5. Previous baby hospitalization history 6. Recent adverse conditions 7. Psychological problems of the father

Intervention groups

1: Intervention group: 36 fathers with premature infants admitted Creating and establishing skin contact of a premature infant with their fathers sitting for half an hour 2: Control group: 36 fathers with premature infants admitted Routine appointments, in this group skin contact with fathers is not established

Main outcome variables

Fathers' anxiety level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200107046040N1**

Registration date: **2020-12-14, 1399/09/24**

Registration timing: **retrospective**

Last update: **2020-12-14, 1399/09/24**

Update count: **0**

Registration date

2020-12-14, 1399/09/24

Registrant information

Name

Aliasghar Panabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3525 8608

Email address

aliasghar.panabadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-27, 1398/12/08

Expected recruitment end date

2020-06-15, 1399/03/26

Actual recruitment start date

2020-02-27, 1398/12/08

Actual recruitment end date

2020-06-15, 1399/03/26

Trial completion date

2020-06-15, 1399/03/26

Scientific title

Evaluation of the first skin contact father with their preterm infants admitted to Neonatal Intensive Care Unit (NICU) ward

Public title

Evaluation of the first skin contact father with their preterm infants admitted to Neonatal Intensive Care Unit (NICU) ward of Shohada Kargar Hospital on their anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Calendar age (2 to 5 days) The baby has physiologically stable conditions Fetal age under 37 weeks Absence of nicotine or caffeine by the father one hour before enrollment (due to the possible effect of these substances on anxiety)

Exclusion criteria:**Age**

From **2 days** old to **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were divided into test and control groups in pairs and individually (one in between), so that the first infant was divided into the experimental group and the second infant into the control group, and so on.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a trained research colleague was used to make skin contact and the researcher did not know about it.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Yazd Imam Shahr Kargar Blvd. North Sajjad St. Alley 16 corner of Ayatollah Sadr

City

Yazd

Province

Yazd

Postal code

8917777494

Approval date

2020-02-26, 1398/12/07

Ethics committee reference number

IR.SSU.REC.1398.239

Health conditions studied**1****Description of health condition studied**

Skin-to-skin contact

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fathers Anxiety Level

Timepoint

At the beginning of the study before the intervention and immediately after the intervention in both groups

Method of measurement

The level of anxiety in the experimental and control groups before and after the intervention was determined using the Spielberger Anxiety Questionnaire.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After introducing and presenting the necessary explanations about the goals and methods of research and ensuring the confidentiality of information, written and informed consent was received in two copies. . Then, before starting the intervention, the individuals completed the Spielberger STAI form of the situational anxiety-trait questionnaire and the demographic profile form (the infant profile was completed by the researcher from the patient file).). For 30 minutes (based on similar studies) they were exposed to skin-to-skin contact with

infants who had stable conditions according to inclusion criteria. In this way, the naked baby was placed on the skin of the father's abdomen, which in this type of contact, no face-to-face communication was established between the father and the baby and only brought the benefits of skin-to-skin contact. The time of sampling and intervention was between 11 and 17 o'clock. During the skin contact of the baby, the nurse was present to control the baby's symptoms by observation. The parameters of blood oxygen saturation, heart rate, respiration rate are monitored by the nurse. Immediately after skin-to-skin contact, the questionnaire was completed again by individuals.

Category

Behavior

2

Description

Control group: Control group: After introducing and presenting the necessary explanations about the goals and methods of the research and ensuring the confidentiality of the information, written and informed consent was received in two copies. Then, before beginning the intervention, individuals completed the Spielberger STAI Formal-Characteristic Anxiety Questionnaire and the Demographic Characteristics Form (the infant profile was completed by the researcher from the patient's record). Minutes in this group, no skin contact with fathers. Immediately after leaving, the questionnaire was completed again by individuals.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Kargar Hospital

Full name of responsible person

Ali Asghsar Panabadi

Street address

Yazd - Ayatollah Modarres Boulevard

City

Yazd

Province

Yazd

Postal code

۳۸۲۰۰۰۷

Phone

+98 35 3182 2000

Email

shohadakargar.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Yazd, Bahonar Square, the headquarters of Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, third floor

City

yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

+98 35 3726 3733

Email

ayazi.pajooohan@gmail.com

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

khadijeh dehghani

Position

Faculty member of the nursing department

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yazd - Safaieh - Timsar Fallahi St. - Bouali Alley School of Midwifery Nursing

City

yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 1751

Email

dehghanish@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

khadijeh dehghani

Position

Faculty member of the nursing department

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yazd - Safaieh - Timsar Fallahi St. - Bouali Alley School of Midwifery Nursing

City

yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 1751

Email

dehghanish@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

khadijeh dehghani

Position

Faculty member of the nursing department

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yazd - Safaieh - Timsar Fallahi St. - Bouali Alley School of Midwifery Nursing

City

yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 1751

Email

dehghanish@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

...

When the data will become available and for how long

Access period starts from 1399

To whom data/document is available

It will be available to researchers working in academic and scientific institutions and to people working in industry.

Under which criteria data/document could be used

...

From where data/document is obtainable

...

What processes are involved for a request to access data/document

...

Comments