

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of skin to skin contact between biological mother and the neonate born from surrogate mother immediately after birth on her attachment behaviors

Protocol summary

Study aim

Determine of the effect of skin to skin contact between biological mother and the neonate born from surrogate mother immediately after birth on her attachment behaviors.

Design

Clinical trial with 2 interference and control groups, single blind, nonrandomized on 50 mothers

Settings and conduct

Clinical trial semi experience, with post test and single blind. Infertility women who take surrogate mother in Tehran hospitals and infertility centers are goal of study.

Participants/Inclusion and exclusion criteria

Participants include: Infertility women who helped from surrogate mother and without any mental disorders that their infants were born in term full and do not need of special cares.

Intervention groups

The intervention group is biological mothers who have skin-to-skin contact with the baby after the birth of their surrogate uterus. After teaching skin-to-skin contact to biological mothers, after birth, the infant is placed in the surrogate womb immediately on the biological mother's bare breasts, and then for a quarter of the biological mother's behavior with the baby by two observers before discharge from the hospital. (Researcher and a colleague) is observed and recorded in the Avant questionnaire. In the control group, there is no skin contact between the biological mother and the baby, and before the baby is discharged, the mother's behavior with him is observed and recorded according to the mentioned method, and finally the scores obtained in each group are compared and analyzed.

Main outcome variables

Attachment score based on Avant questionnaire (emotional-proximity-caring behaviors)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051318N1**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **prospective**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Robabe Masoomi Disfani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7799 8927

Email address

tahere6758@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of skin to skin contact between biological mother and the neonate born from surrogate mother immediately after birth on her attachment behaviors

Public title

The effect of skin to skin contact on attachment behaviors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women who have defects in their womb structure One year must be passed after marriage and the effort for pregnancy They should be mentally in a well shape for cooperation Birth of infants in period of 37-42 weeks APGAR score 9-10 in 5-10 minutes after the birth

Exclusion criteria:

Lack of permission and cooperation from the biological mother Mothers, being with depression and mental problems Birth of infants who have less than 37 weeks Newborns with respiratory problems and need of special cares

Age

From **9 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Considering the fact that putting samples in 2 groups of control and interference can not occur accidentally, samples were directed in their correct group only by post test and single blind.

Placebo

Not used

Assignment

Parallel

Other design features

This study is a quasi-experimental clinical trial study (considering that the allocation of samples to the control and intervention groups is not random) as a post-test only and a blind side (statistical analyst)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran university of Medical Sciences

Street address

East nosrat st, Doctor mirkhani st, Tohid square

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Tehran

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Postal code

1419733171

Approval date

2021-02-05, 1399/11/17

Ethics committee reference number

IR.TUMS.FNM.REC.1399.197

Health conditions studied

1

Description of health condition studied

The effect of skin to skin contact between biological mother and the neonate born from surrogate mother immediately after birth on her attachment behaviors

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Attachment score of biologic mother with newborn based on Avamet questionnaire

Timepoint

After delivering newborn to biologic mother and before discharge from hospital

Method of measurement

Avamet questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Biologic mothers who had contacted with their newborn after birth of surrogate mother. In order to achieve the objectives of the research, the form of collecting personal information and the scale of attachment of mother and infant after birth (Avant) are used. For the intervention group during a session on skin contact and its effects in accordance with the National Instruction of the Ministry of Health, the Deputy Minister of Treatment if available face to face in the first meeting and if not available by providing an educational CD

prepared in accordance with The Ministry of Health's national guidelines will be taught before the baby is born, through a nurse or midwife appointed by the health center to assist the researcher.

Category

Behavior

2**Description**

Control group: To collaborate in this study, mothers are selected using available sampling and then divided into two groups of skin contact and non-skin contact (control group). This division is not accidental because, in some infertility centers, after delivery from the surrogate mother, the baby comes into skin contact with the biological mother, while in some centers this is not the case. As a result, the researcher is not able to randomize individuals into two groups of intervention and control due to the internal protocols of these centers.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran private hospitals that have Infertility and delivery section

Full name of responsible person

Robabe Masoomi Disfani

Street address

Bahman hospital, Iran zamin st, Qods town

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1465795481

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Email

info@gahmanhospital.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahrayian

Street address

Technology and investigation assistant, 6th floor, central organization of the university, Qods St, Keshavarz Blvd

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msahrai@tums.ac.ir

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

No

Title of funding source

Tehran university of medical science

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

Robabe Masoomi Disfani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Tehran University of Medical Sciences

Full name of responsible person

Robabe Masoomi Disfani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Title and more details about the data/document

Except for given name and family name, all other data of participants will be released.

When the data will become available and for how long

Starting of the period, after 6 months.

To whom data/document is available

The researchers in scholar and scientific departments.

Under which criteria data/document could be used

The researchers in scholar and scientific departments.

From where data/document is obtainable

Robabe Masoomi Disfani/Tahere6758@gmail.com

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

The process is not clarified yet.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Robabe Masoomi Disfani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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