

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Influence of Rooming-in techniques and mode of delivery on early mother infant bonding

Protocol summary

Study aim

To compare the effect rooming-in practices and vaginal birth versus cesarean delivery on the quality of early mother-infant bonding during the immediate postpartum period

Design

quasi-experimental design

Settings and conduct

PNS HAFEEZ

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primigravida aged 18 to 40 years, with a single, full-term pregnancy (38-42 weeks of gestation), classified as American Society of Anesthesiologists (ASA) physical status II planned for vaginal delivery . Exclusion criteria: Women were excluded who had multiple gestation (twins or triplets), known major fetal anomalies or a history of significant psychiatric illness

Intervention groups

Group-VD (vaginal delivery) Group-CD (cesarean delivery)

Main outcome variables

PBQ SCORE

General information

Reason for update

Acronym

MIB trial

IRCT registration information

IRCT registration number: **IRCT20231202060236N1**

Registration date: **2026-08-05, 1405/05/14**

Registration timing: **retrospective**

Last update: **2026-08-05, 1405/05/14**

Update count: **0**

Registration date

2026-08-05, 1405/05/14

Registrant information

Name

Kaukab Majeed

Name of organization / entity

Rawalpindi medical university, Pakistan

Country

Pakistan

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+92 345 6032001

Email address

kaukabsharjeel@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-01, 1403/12/11

Expected recruitment end date

2026-02-01, 1404/11/12

Actual recruitment start date

2025-03-01, 1403/12/11

Actual recruitment end date

2026-02-01, 1404/11/12

Trial completion date

2026-02-02, 1404/11/13

Scientific title

Influence of Rooming-in techniques and mode of delivery on early mother infant bonding

Public title

Influence of Rooming-in techniques and mode of delivery on early mother infant bonding

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravida aged 18 to 40 years, full term pregnancy
ASA-II

Exclusion criteria:

multipara patients with psychiatric disorders patients
with co-morbid conditions

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **133**

More than 1 sample in each individual

Number of samples in each individual: **98**

two groups basis on mode of delivery

Actual sample size reached: **210**

More than 1 sample in each individual

Actual sample size in each individual: **98**

vaginal delivery and cesarean delivery

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Blinding: Due to the nature of the study, complete blinding was not feasible. Participants (mothers) were aware of their mode of delivery and rooming-in status, and the healthcare providers (obstetricians, nurses, and midwives) responsible for routine maternal and neonatal care were also aware of these interventions as they were part of standard clinical management. The principal investigator supervised recruitment and data collection but did not influence clinical management or allocation to study groups. Data collectors administered the questionnaires using a standardized protocol without influencing participants' responses. Outcome assessment was based on the validated Postpartum Bonding Questionnaire (PBQ), which was completed by the mothers themselves, thereby minimizing assessor bias. During statistical analysis, datasets were coded and group identifiers were anonymized so that the statistician remained blinded to group allocation until completion of the primary analysis. A Data Safety and Monitoring Board was not constituted because this was a non-interventional observational study with no experimental intervention or safety concerns. Manuscript preparation and interpretation of results were performed after completion of the blinded statistical analysis using anonymized group codes.

Placebo

Not used

Assignment

Parallel

Other design features

improvement of practices

Secondary Ids

empty

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

PNS HAFEEZ NAVAL HOSPITAL

Street address

PNS HAFEEZ

City

ISLAMABAD

Postal code

44000

Approval date

2025-01-01, 1403/10/12

Ethics committee reference number

IERB/PN/1621

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

mother-infant bonding after delivery

ICD-10 code

mother, in

ICD-10 code description

ICD-10

2**Description of health condition studied**

mother infant bonding

ICD-10 code

mother, in

ICD-10 code description

mother infant bonding

Primary outcomes**1****Description**

PBQ score

Timepoint

after application of intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

successful breast feeding

Timepoint

after intervention

Method of measurement

observation

Intervention groups

1

Description

Intervention group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

PNS Hafeez Naval hospital

Full name of responsible person

Dr khalida parveen

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Hospital resources

Grant code / Reference number

01

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

Yes

Title of funding source

PNS HAFEEZ

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

PNS HAFEEZ

Full name of responsible person

Khalida Parveen

Position

consultant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable