Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 delivey)
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

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Kaukab Majeed
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Rawalpindi medical university, Pakistan
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Pakistan
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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
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PNS HAFEEZ
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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
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Person responsible for updating data

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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