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Can MINAR, a locally made infant warming bed safely support newborn resuscitation compared with the standard device used in hospitals?

Submission date
11/01/2026

Recruitment status
No longer recruiting

Registration date
14/01/2026

Overall study status
Completed

Last Edited
12/01/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration.

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Study information

Scientific Title
A randomized non-inferiority study comparing the MINAR™ infant warmer resuscitator with the Dräger Resuscitaire® for clinical feasibility and safety outcomes in neonates requiring delivery room resuscitation

Study objectives
This study aims to assess the clinical feasibility and non-inferiority of the MINAR™ Infant Warmer Resuscitator compared with the Dräeger Resuscitaire®, the current standard in our center, by evaluating safety, effectiveness, and key resuscitation outcomes, including APGAR score progression, Downe score–guided respiratory support, and immediate post-resuscitation parameters.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/07/2025, The Research Ethics Committee of Dr. Hasan Sadikin General Hospital Bandung (Jalan Pasteur no.38, Bandung, 40161, Indonesia; +62222034953; https://web.rshs.go.id/), ref: DP.04.03/D.XIV.6.5/341/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Neonates requiring delivery room resuscitation or stabilization due to respiratory compromise, including apnea, bradycardia, respiratory distress, or persistent cyanosis, necessitating oxygen supplementation and/or ventilatory support.

Interventions
This study is conducted as an interventional, two-arm, parallel-group clinical feasibility study comparing the MINAR™ Infant Warmer Resuscitator with the Dräger Resuscitaire® as the comparator device. Eligible neonates are allocated in a 1:1 ratio using a quasi-randomization method with alternating allocation, whereby participants are sequentially assigned to the MINAR or Dräger group based on their order of registration at birth.

In both study arms, the assigned infant warmer resuscitator bed is prewarmed prior to use according to the manufacturer's instructions. Immediately after birth and completion of the initial steps of neonatal resuscitation, the neonate is placed on the allocated resuscitator bed. At 5 minutes after placement, the warmer setting is adjusted to a target temperature of 36.5 °C to maintain normothermia.

Oxygenation and ventilation are delivered in both groups in accordance with standard neonatal resuscitation protocols, consistent with current Neonatal Resuscitation Program (NRP) and World Health Organization (WHO) guidelines. Respiratory support, including supplemental oxygen, continuous positive airway pressure, or positive pressure ventilation, is provided as clinically indicated using the integrated resuscitation system of each device.

The intervention period is 60 minutes. During this period, heart rate, respiratory rate, oxygen saturation (SpO_2), and body temperature are continuously monitored using the built-in sensors of the assigned resuscitator bed. In addition, the Downe score and APGAR score are assessed by trained clinicians at 5, 10, 15, 30, and 60 minutes following initiation of resuscitation.

All interventions and assessments are performed by healthcare personnel trained in neonatal resuscitation. Standardized institutional protocols are followed to ensure patient safety, procedural consistency, and comparability between study groups.

Intervention Type
Device

Phase
Phase 0

Drug/device/biological/vaccine name(s)

MINAR™ Infant Warmer Resuscitator, Dräger Resuscitaire®

Primary outcome(s)
1. Heart rate measured using a heart rate sensor at 5 , 10, 15, 30, and 60 minutes after neonates are placed on the bed

2. Respiratory rate measured using a respiratory rate sensor at 5 , 10, 15, 30, and 60 minutes after neonates are placed on the bed

3. Peripheral oxygen saturation measured using an SpO2 sensor at 5 , 10, 15, 30, and 60 minutes after neonates are placed on the bed

4. Early neonatal clinical adaptation measured using the APGAR Score at 5 , 10, 15, 30, and 60 minutes after neonates are placed on the bed

5. Severity of neonatal respiratory distress measured using the Downe Score at 5 , 10, 15, 30, and 60 minutes after neonates are placed on the bed

Key secondary outcome(s))

Completion date
26/10/2025

Eligibility

Key inclusion criteria
1. Live-born neonates, delivered by vaginal delivery or caesarean section, who required resuscitation or stabilization following completion of initial steps of neonatal resuscitation.
2. Requirement for oxygen supplementation and/or ventilatory support, defined by one or more of the following criteria in accordance with NRP and WHO guidelines:
2.1. Apnea or gasping respiration
2.2. Heart rate <100 beats per minute after initial steps
2.3. Clinical signs of respiratory distress (e.g., nasal flaring, chest retractions, grunting)
2.4. Persistent central cyanosis despite initial airway positioning and stimulation
3. Neonates managed using an infant warmer resuscitator bed during delivery room or immediate postnatal stabilization.
4. Informed consent obtained from parents or legal guardians.

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
27 days

Sex

All

Total final enrolment
38

Key exclusion criteria
Not meeting key inclusion criteria

Date of first enrolment
04/08/2025

Date of final enrolment
26/10/2025

Locations

Countries of recruitment
Indonesia

Sponsor information

Organisation
Bhakti Bersama Roartha, Ltd.

Funder(s)

Funder type

Funder Name
Universitas Padjadjaran

Alternative Name(s)
Padjadjaran University, UNPAD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			12/01/2026	No	No