Official Study Title:

Nesting Technique for Pain Management During Heel Prick in Term Neonates

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Study Protocol

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STUDY PROTOCOL

Study Description

This randomized controlled experimental trial aims to evaluate the effect of the nesting technique on behavioral and physiological outcomes in term newborns undergoing routine heel-prick blood sampling.

Primary and secondary outcomes include pain scores, crying duration, respiratory rate, heart rate, and oxygen saturation (SpO_2), measured at three predefined time points:

- Baseline (end of 3-minute pre-procedure period)
- During the heel-prick procedure
- Recovery (end of 3-minute post-procedure period)

Study Design

- Study Type: Interventional
- Allocation: Randomized
- Intervention Model: Parallel Assignment
- Masking: No blinding of intervention administrators or outcome assessors
- Primary Purpose: Prevention / Supportive Care

Participants

Inclusion Criteria

- Term newborns (37–42 weeks gestation)
- Birth weight between 2500 g and 4000 g
- Undergoing routine heel-prick blood sampling
- Not receiving any medications
- Clinically stable
- Parental written informed consent provided

Exclusion Criteria

- Preterm or post-term newborns
- Birth weight < 2500 g or > 4000 g
- Presence of any medical condition affecting physiological or behavioral responses
- Clinically unstable infants
- Receiving medication
- Parental refusal or withdrawal of consent

Sample Size

Sample size calculation was based on Neonatal Infant Pain Scale (NIPS) scores at the third measurement time point.

- Effect size (Cohen's d): 0.83
- Confidence level: 95% ($\alpha = 0.05$)
- Statistical power: 80% ($1-\beta = 0.80$)
- Required sample: 25 newborns per group

The study was completed with:

- Intervention group: 29 newborns
- Control group: 30 newborns
- Total sample size: 59 newborns

Randomization and Allocation Concealment

Randomization was performed by an independent researcher using computer-generated random numbers via Random.org.

Group assignments were placed in sealed, opaque envelopes. Each envelope was opened immediately before data collection for each newborn to ensure allocation concealment and minimize selection bias.

Intervention

Experimental Group – Nesting Technique

The nesting intervention was initiated at least 3 minutes before the heel-prick procedure and maintained throughout the procedure and for 3 minutes post-procedure.

Infants were positioned supine with full-body support using standardized cotton-covered, hypoallergenic silicone-filled nesting pillows.

Positioning characteristics:

- Head in midline
- Upper and lower extremities in slight flexion
- Symmetrical positioning
- Gentle upper body coverage without pressure
- No restriction of breathing or circulation

The technique is not part of routine care and was implemented exclusively for research purposes.

Control Group – Standard Care

Infants were kept in their natural supine position without structured positioning support.

Measurements were conducted:

- After 3 minutes pre-procedure
- During heel prick
- After 3 minutes post-procedure

No additional non-pharmacological pain relief methods were routinely used in either group.

Outcome Measures

Primary Outcome

Mean Total Score on the Neonatal Infant Pain Scale (NIPS)

Description:

The NIPS assesses six indicators (facial expression, crying, breathing pattern, arm movements, leg movements, and state of arousal). Total scores range from 0 to 7, with higher scores indicating greater pain.

Time Frame:

Baseline (end of 3-minute pre-procedure period), during heel prick procedure, and at the end of the 3-minute post-procedure period.

Secondary Outcomes

1. Mean Heart Rate (beats per minute)
2. Mean Respiratory Rate (breaths per minute)
3. Mean Oxygen Saturation (SpO_2, %)
4. Crying Duration (seconds)

Time Frame for all secondary outcomes:

Baseline (end of 3-minute pre-procedure period), during heel prick procedure, and at the end of the 3-minute post-procedure period.

Data Collection Instruments

- Infant Information Form (gestational age, birth weight, sex, delivery mode)
- Observation Form (physiological and behavioral parameters)
- Neonatal Infant Pain Scale (NIPS)

Measurements:

- Heart rate and SpO_2: neonatal pulse oximeter
- Respiratory rate: chest observation for 1 full minute
- Crying duration: stopwatch measurement

Heel lances were performed 30–45 minutes after feeding while infants were awake or in light sleep.

Statistical Analysis

- Descriptive statistics: frequency, percentage, mean, standard deviation

- Normality test: Kolmogorov-Smirnov
- Independent Samples t-test: between-group comparisons
- Repeated Measures ANOVA: time-based comparisons
- Significance level: $p \leq 0.05$

Ethical Considerations

The study was approved by the Clinical Research Ethics Committee of Mersin University (Approval No: 2023/833). The research was conducted in accordance with the ethical principles of Mersin University and complied with the Declaration of Helsinki (1964), as revised in 2013.

Written and verbal informed consent was obtained from the parents of all participating newborns prior to enrollment in the study. Participation was voluntary, and parents were informed of their right to withdraw their infant from the study at any time without any effect on clinical care.