Intranasal Fentanyl in Preterm Infants Undergoing PICC Placement: A Feasibility Randomized Controlled Trial

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Introduction

- Preterm infants are subjected to multiple painful procedures as part of clinical care.
- Early and repeated exposure to pain is associated with negative consequences including alterations in brain development and pain hypersensitivity.
- Peripherally inserted central catheter (PICC) placement is a clinically essential painful eliciting moderate to severe pain responses.
- Despite the deleterious effects of pain, pain management strategies are underutilized for PICC placement.
- Intranasal (IN) fentanyl is a promising medication delivering rapid targeted analgesia.

Objectives and Methods

To determine the feasibility of conducting a full-scale RCT evaluating IN fentanyl for PICC placement.

Outcomes:

1. Recruitment (target 4 infants per month)
2. Completeness of pain assessments (target 80%)
3. Adverse events

- A single centre blinded RCT assigned preterm infants to either IN fentanyl or placebo (add-on to standard care) using a computerized random number generator with a 1:1 allocation ratio.
- Study investigators, parents, NICU care providers, and outcome assessors were blinded.
- Descriptive analyses were conducted.

Results

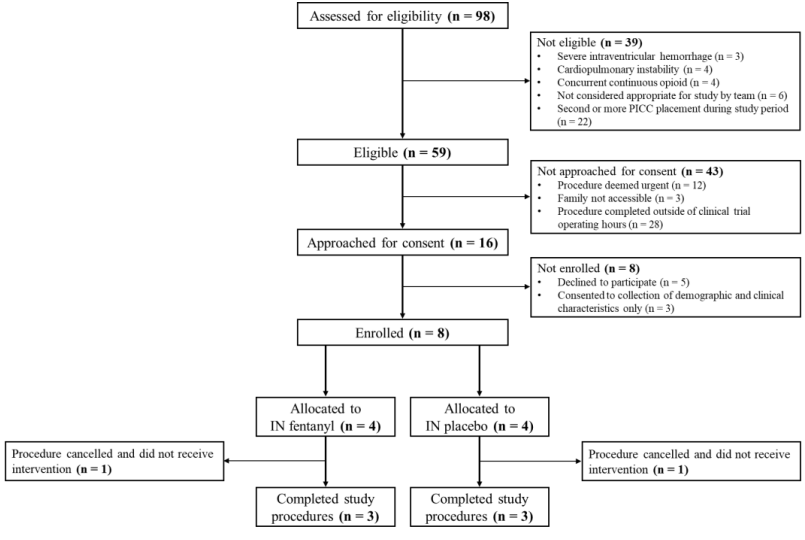

Figure 1: CONSORT participant flow diagram over the 6-month study period

Table 1: Feasibility and clinical outcomes

Outcome	Target	Result
Consent rate	50%	50% (95% CI 28, 72)
Recruitment rate	4 infants per month	1 infant per month
Success rate of video recordings for pain score assessment	80%	100% (95% CI 61, 100)
Adverse events	0	0

Conclusion

A definitive RCT would be feasible with modifications to the recruitment strategy where screen failures are minimized by the expansion of clinical trial operating hours. Pain score assessments were completed successfully and there were no adverse events.

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