Premi-Remi Study

Study to determine whether Remifentanil is effective for treating procedural pain in neonates?

Background

Neonates with conditions such as prematurity, birth defects and infections may require prolonged hospitalisation and multiple painful invasive procedures as part of their medical care. In particular, many of these babies require insertion of peripherally inserted, percutaneous intravenous central catheters (PICCS) to maintain long term vascular access for medications and nutrition.

There is accumulating evidence that, particularly during the critical phase of neurological maturation, controlling the pain associated with medical procedures is beneficial with respect to short term and perhaps longer term outcomes. There is an urgent need to develop pharmacological strategies that more effectively decrease pain without increasing neonatal morbidity.

Remifentanil is an esterase metabolised (so not dependent on the immature liver enzymes) opiod analgesic with rapid onset and an effective biological half-life of 3 – 10 mins. Its theoretical advantage is that it may provide the superior analgesia of an opiod without causing prolonged respiratory depression.

AIM: to determine whether Remifentanil is effective for treating procedural pain in neonates?

Inclusion Criteria

- Medically stable neonates
- Inpatient in JHCH NICU Level 3 Nursery
- Who require insertion of a central venous catheter for their medical care
- ≥28–44 weeks corrected gestational age at the time of procedure
- Parental consent

Exclusion Criteria

- Major congenital anomalies
- Severe hypoxic ischaemic encephalopathy
- Current clinical seizures
- Concomitant muscle relaxant
- Opioid dependence
- Emergency central line insertions
- Lack of venous access for administration of study drug

What does the study involve?

This is a randomised double-blind controlled clinical trial with 2 treatment arms: enrolled neonates will be randomly allocated to receive either IV remifentanil infusion or placebo (5% Dextrose infusion). The infusion commences 15mins prior to commencement of procedure (insertion of PICC) and continues until procedure is complete. All neonates' faces are video taped during the procedure and pain scoring is measured by means of Premature Infant Pain Profile (PIPP) by both the bedside nurse and an independent reviewer. Physiological data including blood pressure, heart rate, respiratory rate and oxygen saturation are downloaded from monitors and recorded.

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