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Intranasal versus intravenous naloxone in pediatric opioid poisoning: A pilot randomized clinical trial

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Aim and objectives: To evaluate nasal naloxone in pediatric patients with opioid poisoning by measuring the time from the treating physician's decision to administer antidote to return of normal respiration. The hypothesis was that nasal administration of naloxone is not clinically inferior to intravenous administration if the time it takes to place a secure intravenous line is taken into account. **Methodology:** In a non-inferiority hospital-based randomized pilot clinical trial, n=40 pediatric opioid-poisoned children were assigned in a 1:1 ratio to receive either intravenous (0.8 mg/ 2mL) or intranasal (1.4mg/0.1ml) naloxone hydrochloride in addition to basic first aid. The time from physician's decision to treat with antidote to the return of normal respiration was the primary outcome. Adverse events, need for additional naloxone, re-intoxication, patient and staff satisfaction were also recorded. **Results:** Twenty-nine (72.5%) children (median age: 27 months), had abnormal respiration and all of them had reduced consciousness at the time of admission. After intervention, all cases in both groups responded to naloxone administration, while two cases (one in each group) required an additional naloxone IV dose. IV cannula insertion took a median of 35 seconds (IQR 25, 49). Decision to administer



naloxone, IV cannulation plus response to naloxone was 68 seconds (IQR 50, 82) in intravenous group and 23 seconds (IQR 20, 52) in the intranasal group.

Conclusions: The pilot study shows that IN naloxone is not clinically inferior to IV in terms of time to clinical response if the time effort for IV cannulation is considered.