Methods We conducted a prospective, single centre, open-label pharmacokinetic study in infants 1–3 months undergoing sepsis workup in the emergency unit. Included infants received alternating nalbuphine as 0.05 mg/kg intravenous bolus or as 0.1 mg/kg intranasal spray. PK samples were taken at 3 pre-defined time points (15, 30 and max. 240 min post-dose before discharge). Area under the concentration-time curve (AUC0–Tlast and AUC0–infinity for i.v.) was calculated using non-compartmental analysis and was compared between groups using Wilcoxon test. Further parameters derived included maximum concentration (Cmax), time of maximum concentration (Tmax for i.n.) and terminal half-life (t1/2).

Results A total of 31 patients were included in the analysis. Median age was 55 days [interquartile range 38–63] in the intranasal (N=20) and 42 [37–76] days in the iv group (N=11). Median AUC0–Tlast was 7.6 [5.4–10.4] mcg·h/L following intranasal versus 7.9 [6.0–14.7] mcg·h/L for iv administration (p=0.46). AUC0–Tlast (i.v.) covered 80 [68–83]% of AUC0–infinity. Median Cmax was 4.5 [3.5–5.6] mcg/L (i.n.) versus 6.5 [5.3–15.9] mcg/L (i.v.) (p=0.014), t1/2 was 2.4 [1.3–2.8] h (i.n.) versus 1.3 [1.1–1.5] h (i.v.) (p=0.021). Tmax occurred 37 [32–65] min after intranasal administration.

Conclusion This first PK study of intranasal nalbuphine in infants suggests that 0.1 mg/kg i.n. dosing provides similar exposure as 0.05 mg/kg i.v. in infants in terms of AUC, and hence intranasal bioavailability close to 50%.

Disclosure(s) Nothing to disclose