The effect of intravenous Aminophylline on preventing AKI in sick neonates – A multicentric double blinded, randomised, placebo-controlled clinical trial

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Introduction

Neonatal AKI = high mortality

Aminophylline
Adenosine receptor antagonist
↑Renal blood flow / ↑Natriuresis

Study Design

- Multicentre (3 NICUs) Double-Blind
- Randomised Controlled Trial
- Critically - ill neonates (N = 110)
- ≥ 36 weeks of gestation
- SNAPPE II ≥ 37

Intervention

IV Aminophylline
8 mg/kg
n = 54

Vs

Placebo
n = 56

At 12 hours of NICU admission

Outcome Measures

Primary Outcome
AKI at Day 3 (modified neonatal KDIGO)

Secondary Outcomes
AKI at Day 7 / Δ Urinary NGAL & FeNa (48h)
Mortality
Length of stay

Results

Primary Outcome – AKI at Day 3

Aminophylline 31.5% Vs Placebo 35.7%

RR 0.88 (95% CI 0.52–1.49)

Other Outcomes

AKI at Day 7 : 14.8% vs 8.9%
RR 1.66 (95% CI 0.58–4.75)

Biomarkers : Δ uNGAL (p = 0.58) / FeNa (p = 0.58)

Mortality : 9.3% Vs 7.1%

Length of stay : No difference

No significant difference in 1⁰ and 2⁰ outcomes

Conclusion: Single-dose IV aminophylline was safe but did not significantly reduce AKI, improve biomarkers, or lower mortality in critically ill term neonates. A possible early signal warrants larger, adequately powered trials.

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