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Amoxicillin equivalent to parenteral antibiotics in the treatment of resource-deficient infants with tachypnea

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Abstract

African Neonatal Sepsis Trial (AFRINEST) group, Tshefu A, Lokangaka A, Ngaima S, Engmann C, Esamai F, Gisore P, et al. Oral amoxicillin compared with injectable procaine benzylpenicillin plus gentamicin for treatment of neonates and young infants with fast breathing when referral is not possible: a randomised, open-label, equivalence trial.

Question

Among young infants with tachypnea and in the absence of other signs of serious infection, what is the therapeutic efficacy of oral amoxicillin, compared with injectable procaine benzylpenicillin–gentamicin, in tachypnea resolution?

Design

Randomized, open-label, equivalence trial.

Setting

5 community-based sites in DR Congo, Kenya, and Nigeria.

Participants

Infants aged 0-59 days with fast breathing as the only sign of serious illness whose parents did not accept hospital referral.

Intervention

Oral amoxicillin vs injectable procaine benzylpenicillin–gentamicin.

Primary Outcome

Treatment failure by day 8 after enrollment.

Main Results

Amoxicillin demonstrated equivalence with benzylpenicillin-gentamicin: absolute risk reduction, per protocol analysis 2.6% (95% CI –6.0 to 0.8), intention-to-treat analysis 1.8% (95% CI –5.0 to 1.5).

Conclusions

Young infants with tachypnea can be effectively managed in a setting where referral is not possible.

Commentary

World Health Organization guidelines for the treatment of young infants with possible serious bacterial infection recommend inpatient care with parenteral antibiotics.¹ In Sub-Saharan Africa, where infant mortality is particularly high, poor access to health facilities is a major barrier to care. This rigorously conducted multicenter trial demonstrated equivalence between oral and injectable therapy—findings that are consistent with existing evidence from Asian countries.^{2,3} Results of this study provide important data for use in the development of evidence-based guidelines for the management of sick young infants in low-income settings. National programs considering incorporating the findings of this study into policy will need to consider the feasibility of: (1) effective community-based follow up; (2) education of caregivers on signs of clinical deterioration; and (3) strengthening the training of health workers to exclude other signs of severe illness associated with high mortality (eg, hypoxia). Despite the low mortality reported, these findings do not obviate the need to improve access to inpatient services for severely-ill young infants, in whom mortality is generally high.