

Azithromycin Treatment for Respiratory Syncytial Virus-induced Respiratory Failure in Children

NCT05026749

Status	RECRUITING
Phase	Phase 3
Sponsor	University of Alabama at Birmingham
Enrollment	370 participants

Key Eligibility Criteria

Inclusion (5)

- Admission to the pediatric ICU with a confirmed diagnosis of RSV infection. RSV infection is based on a positive nasal swab for RSV fluorescent antibody or via multiplex assay or culture;
- Requiring intensive respiratory support defined as either mechanical ventilation or NIV (BiPAP or CPAP) or HFNC (at ≥ 1 L/kg/min of flow
- Enrollment into the study within 48 hours of ICU admission and placement on intensive respiratory support;
- Onset of RSV-related symptoms must be less than 5 days
- Age: Neonates-2 years. For those less than 1 week of age, they must have been discharged home from the hospital after their birth.

Exclusion (8)

- AZM use within 7 days of ICU admission;
- Contraindication to AZM use including known hypersensitivity to AZM, erythromycin, any macrolide, or ketolide drug, patients with significant hepatic impairment (direct bilirubin ≥ 1.5 mg/dL or ALT ≥ 10 times the upper limits of normal);
- Patients with known cardiac disease, cardiac arrhythmia or with electrocardiogram QT interval corrected for heart rate (QTc) ≥ 450 millisecond (ms);
- Intensive respiratory support greater than 48 hours prior to ICU admission;
- Chronic ventilation or supplemental oxygen need at home;

... and 3 more (see full listing online)

Locations (15 total)

The University of Alabama at Birmingham, Birmingham, Alabama, United States
University of California San Francisco, San Francisco, California, United States
Yale School of Medicine, New Haven, Connecticut, United States
... and 12 more locations

<https://clinicaltrials.gov/study/NCT05026749>

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