Safety and Efficacy of Amoxycillin-Clavulanate Oral Suspension in Children with Respiratory Tract Infections: A Phase IV Study

APCCMI2025 BANGKOK

LB-RES-044

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INTRODUCTION AND OBJECTIVES

- The high-dose formulation of Amoxycillin and Potassium Clavulanate oral suspension (600 mg + 42.9 mg/5 mL) has amoxycillin and clavulanate in a 14:1 ratio, providing higher amounts of amoxycillin while maintaining the same daily dose of clavulanic acid as the regular strength formulation.[1]
- The safety and efficacy of Amoxycillin and Potassium Clavulanate oral suspension (600 mg + 42.9 mg/5 mL) in pediatric patients with URTI (tonsillo-pharyngitis, acute bacterial sinusitis, and acute otitis media), or LRTI (lobar pneumonia and/or bronchopneumonia) was evaluated in the current study.

PATIENTS AND METHODS

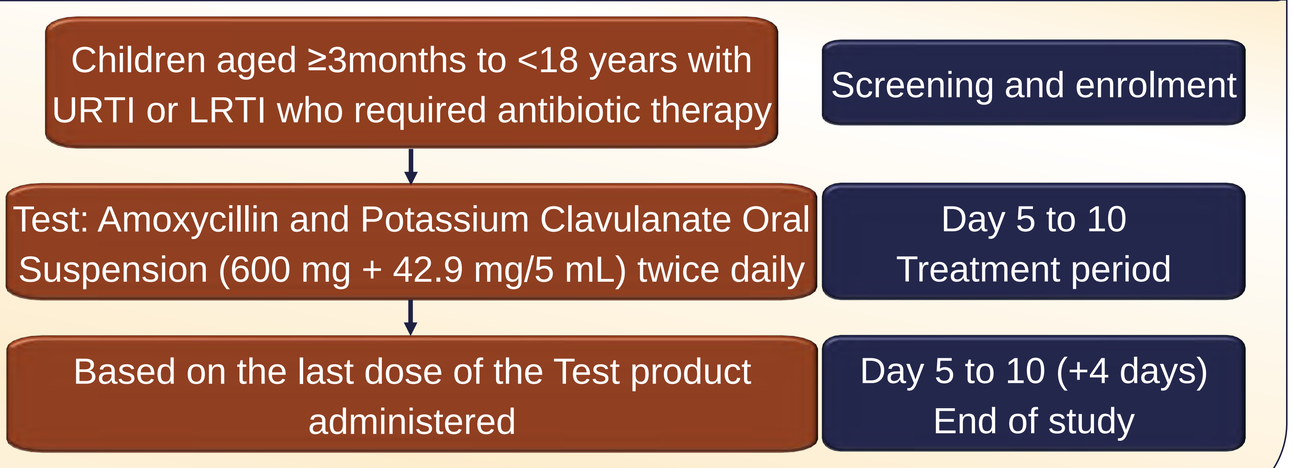
This was a phase IV, multicentre, open-label, single-arm study in India to evaluate the safety and efficacy of Amoxycillin and Potassium Clavulanate oral suspension [Clinical Trial Registration: CTRI/2023/08/056267].

Primary Endpoint:

- To assess the safety of Amoxycillin and Potassium Clavulanate oral suspension in pediatric patients

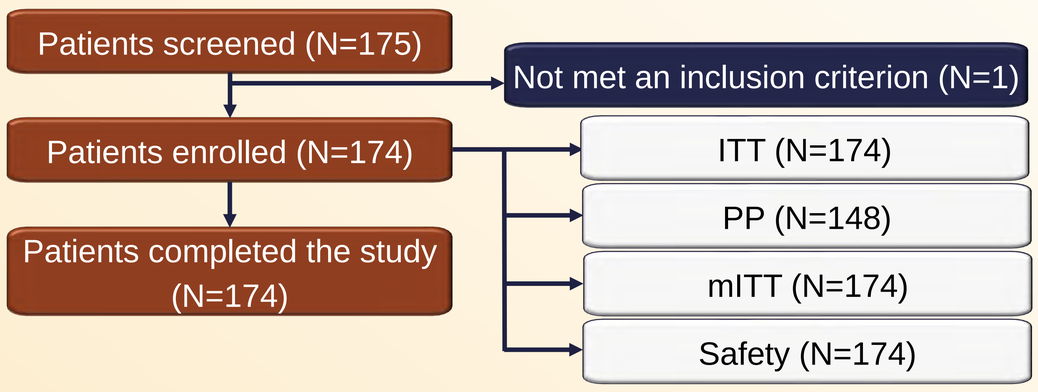
Secondary Endpoints:

- To assess the clinical efficacy (clinical cure, clinical improvement, clinical failure and clinical relapse)
- To assess the time to symptom resolution



RESULTS

Patient disposition



Baseline demographics and characteristics	Overall (174) (ITT population)
Gender, n (%)	**Female:** 73 (42.0) **Male:** 101 (58.0)
Age, years (Mean ± SD)	7.37 ± 4.50
Height, cm (Mean ± SD)	114.3 ± 25.15
Weight, kg (Mean ± SD)	22.20 ± 9.65
Duration of symptoms, days (Mean ± SD)	3.99 ± 2.03
Patients with Tonsillo-pharyngitis, n (%)	86 (49.4)
Patients with Acute Bacterial Sinusitis, n (%)	24 (13.8)
Patients with Acute Otitis Media, n (%)	13 (7.5)
Patients with LRTI, n (%)	51 (29.3)

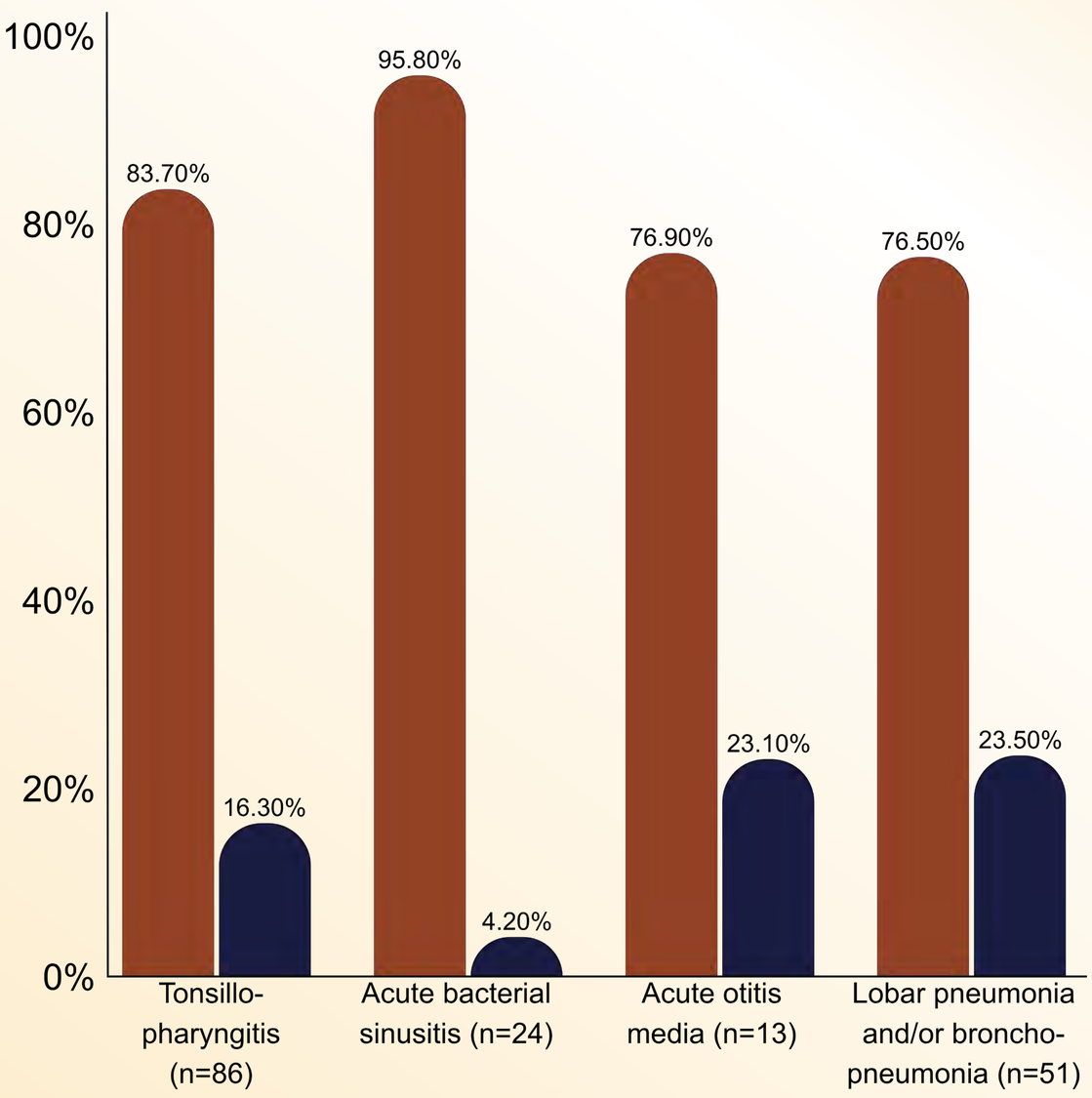
Safety (safety population)

- 23 TEAEs were reported in 21 patients during the study.
- A total of 20 TEAEs were drug-related.
- Diarrhoea was the most common TEAE; 6 patients with tonsillo-pharyngitis and 5 with acute bacterial sinusitis experienced diarrhoea.
- No severe, serious or life-threatening AEs were observed.

System Organ Class Preferred Term	Overall (N=174) Number of AEs	 n (%)
Total AEs	**23**	**21 (12.1%)**
Total TEAEs	**23**	**21 (12.1%)**
Gastrointestinal disorders	20	19 (10.9%)
Abdominal discomfort	3	3 (1.7%)
Abdominal pain upper	3	3 (1.7%)
Diarrhoea	11	11 (6.3%)
Nausea	1	1 (0.6%)
Vomiting	2	2 (1.1%)
Nervous system disorders	3	3 (1.7%)
Headache	2	2 (1.1%)
Sedation	1	1 (0.6%)

Efficacy (mITT population)

Proportion of patients achieving clinical cure and clinical improvement at the end of study



- No patients were reported as clinical failure or with clinical relapse during the study.

Diagnosis	Median duration of time to symptom resolution (days)
Overall (N=174)	**6.00**
Tonsillo-pharyngitis (n=86)	5.00
Acute bacterial sinusitis (n=24)	6.00
Acute otitis media (n=13)	8.00
Pneumonia (lobar and/or broncho-pneumonia) (n=51)	6.00

CONCLUSIONS

In children with URTI or LRTI, treatment with Amoxycillin and Potassium clavulanate oral suspension demonstrated:

- Clinical cure or improvement in all patients
- No cases of clinical failure or relapse
- Acceptable safety and tolerability

In the era of growing antimicrobial resistance, these findings reinforce that Amoxycillin and Potassium clavulanate oral suspension remains a safe, well-tolerated and effective treatment choice for pediatric patients with URTI and LRTI.

AE: Adverse event; **ITT:** Intention to treat; **LRTI:** Lower respiratory tract infection; **mITT:** Modified intention to treat; **N:** Total number of patients; **n:** Number of patients; **PP:** Per protocol; **SD:** Standard deviation; **TEAE:** Treatment-emergent AE; **URTI:** Upper respiratory tract infection; **References: 1.** *Manjula S et al. Int J Contemp Pediatr. 2024 Jul;11(7):916-920*

Poster presented at The 20th Asia Pacific Congress of Clinical Microbiology and Infection (APCCMI 2025) in Bangkok, Thailand, on 2 – 4 November 2025