

Post Authorization Efficacy and Safety Study (PAES) to Confirm and Collect More Clinical Data of Buccalin® Tablets In the Prophylaxis of Recurrent Lower Respiratory Tract Infections (RLRTIs).

NCT06736288

Status	RECRUITING
Phase	Phase 4
Sponsor	Laboratorio Farmaceutico SIT srl
Enrollment	240 participants

Key Eligibility Criteria

Inclusion (13)

- Patients willing and able to provide voluntary informed consent and to follow protocol requirements.
- Male or females from 18 to 99 years old, (Adult, Older Adult).
- Patients with Recurrent LRTIs including tracheitis, tracheobronchitis, acute bronchitis and exacerbations of chronic lung disease (asthma and/or COPD and/or bronchiectasis), who present with both of the following:
 - a) e2 episodes within 12 months prior to the run-in period based on patient reported medical history (to access the run-in period)
 - b) e2 episodes during the run-in period documented by appropriate microbiological diagnostic test (to access the treatment period)
- Patients:
 - ... and 8 more (see full listing online)

Exclusion (41)

- RUN-IN period
- Female patient: pregnant, lactating or planning pregnancy (Female of child-bearing potential will undergo urine pregnancy test).
- Female of potential child-bearing that does not use at least one effective contraceptive method for the entire study.
- Contraindication or known hypersensitivity to the active ingredients of bacterial lysates or any excipients listed in the ingredients.
- Pneumonia (based on the EMA Referral Procedure EMEA/H/A-31/1465).
- ... and 36 more (see full listing online)

Locations (10 total)

AOU Ss. Antonio E Biagio E C. Arrigo, Alessandria, Italy
AOU Policlinico G. Rodolico-San Marco, Catania, Italy
ASST Fatebenefratelli Sacco, Milan, Italy
... and 7 more locations