

Clinical Trial of TQC2731 Injection in Patients With Chronic Sinusitis and Nasal Polyps

NCT07107256

Status	RECRUITING
Phase	Phase 3
Sponsor	Shanghai Chia Tai Tianqing Pharmaceutical Technology Development Co., Ltd.
Enrollment	246 participants

Key Eligibility Criteria

Inclusion (12)

- Signed informed consent form prior to trial participation, demonstrating full understanding of trial objectives, procedures, and potential adverse reactions.
- Age between 18 and 75 years (inclusive) at the time of informed consent signing, regardless of gender.
- Diagnosis of bilateral chronic rhinosinusitis with nasal polyps (CRSwNP) meeting the diagnostic criteria of the "Chinese Guidelines for the Diagnosis and Treatment of Chronic Rhinosinusitis (2018)"
- At least one prior course of systemic corticosteroids (prednisone 0.5-1 mg/kg/day or 15-30 mg/day or equivalent for minimum 5 days) within 2 years before screening, with persistent bilateral CRSwNP; AND/OR contraindication/intolerance to systemic corticosteroids; AND/OR prior nasal polyp surgery performed more than 6 months before screening.
- Bilateral Nasal Polyp Score (NPS) e5 (maximum score 8) with e2 points per nostril, as assessed by nasal endoscopy during screening and randomization.

... and 7 more (see full listing online)

Exclusion (61)

- Conditions/Diseases Affecting Efficacy Evaluation
- Nasal septum deviation causing e1 nostril obstruction
- Perforation of the nasal septum
- Acute sinusitis, nasal infection, or upper respiratory infection within 2 weeks pre-screening or during screening/run-in periods
- Rhinitis medicamentosa

... and 56 more (see full listing online)

Locations (60 total)

Zhongda Hosiptal Southeast University, Fuyang, Anhui, China
The Second Affiliated Hospital of Anhui Medical University, Hefei, Anhui, China
Peking University People'S Hospital, Beijing, Beijing Municipality, China
... and 57 more locations