

The Safety and Efficacy of Sequential Hormone Therapy and IBI311 Therapy in Patients With Active Moderate to Severe TAO in the Initial Treatment.

NCT07152340

Status	RECRUITING
Phase	Phase 4
Sponsor	Shanghai Changzheng Hospital
Enrollment	64 participants

Key Eligibility Criteria

Inclusion (4)

- Diagnosed with TAO by Bartley criteria.
- Moderate to severe patients defined by EUGOGO.
- CAS e4 (on the 7-item scale) for the study eye.
- Have not received glucocorticoid treatment for TAO in the past.

Exclusion (13)

- Anticipated need for intervention due to sight-threatening complications or other significant and acute deterioration in vision.
- Combined with other lesions in the orbit.
- Receive orbital radiotherapy or surgical treatment for TED, including orbital decompression, strabismus surgery and eyelid retraction correction.
- During the screening period, if either ear has a history of tinnitus or other hearing impairment; Or abnormal pure tone audiometry results (defined as an average bone conduction hearing threshold of e25 dB at 0.5, 1, 2, 4 kHz or a bone conduction hearing threshold of e40 dB at any frequency).
- At the time of screening, aspartate aminotransferase (AST) or alanine aminotransferase (ALT) \gt 3 times ULN, or accompanied by active hepatitis B (defined as HBsAg positive with HBV-DNA load greater than 1000 IU/mL), or being receiving anti-hepatitis B virus treatment.

... and 8 more (see full listing online)

Locations (2 total)

Shanghai Changzheng Hospital, Changhua, Shanghai Municipality, China
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