

# Evaluation of the Efficacy and Safety Observation of IBI311 Treatment in Patients With Inactive TAO

NCT07152392

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Status	RECRUITING
Phase	Phase 4
Sponsor	Shanghai Changzheng Hospital
Enrollment	50 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Diagnosed with TAO by Bartley criteria.
- Moderate to severe patients defined by EUGOGO.
- CAS  $\leq 3$  (on the 7-item scale) for the study eye.
- Participant with intractable diplopia, or incomplete closure of both eyes, or requiring further surgical intervention.
- Participant with a strong willingness for further intervention.

### Exclusion (12)

- 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  $\geq 25$  dB at 0.5, 1, 2, 4 kHz or a bone conduction hearing threshold of  $\geq 40$  dB at any frequency).
- At the time of screening, aspartate aminotransferase (AST) or alanine aminotransferase (ALT)  $> 3$  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 7 more (see full listing online)

## Locations (1 total)

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Shanghai Changzheng Hospital, Shanghai, Shanghai Municipality, China