

# A Study of GenSci098 in Subjects With Active Thyroid Eye Disease

NCT06569758

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	Changchun GeneScience Pharmaceutical Co., Ltd.
<b>Enrollment</b>	76 participants

## Key Eligibility Criteria

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### Inclusion (19)

- At the time of signing the informed consent form (ICF): aged between 18 and 75 years (inclusive).
- Diagnosed by the physician as having active TED associated with Graves' disease (GD), based on clinical and laboratory test results, with a CAS e 3 (on the 7-point scale) for the most severely affected eye at screening and baseline.
- Onset of active symptoms and signs of TED (including one or more of the following: redness of conjunctiva, swelling of conjunctiva (chemosis), redness of eyelids, swelling of eyelids, swelling of caruncle or plica, spontaneous retrobulbar pain, and pain on attempted upward or downward gaze) within 12 months prior to the screening visit.
- Positive for thyroid stimulating hormone receptor antibodies (TRAb) at screening.
- Moderate to severe TED (impacting the quality of life, requiring intervention but not threatening vision), usually with at least 2 of the following manifestations: (1) eyelid retraction width e 2 mm, (2) moderate or severe soft tissue involvement, (3) proptosis e 3 mm above normal for race and gender, (4) inconstant or constant diplopia.

... and 14 more (see full listing online)

### Exclusion (23)

- Decreased best corrected visual acuity due to optic neuropathy as defined by a decrease in vision of 2 or more lines on the Snellen chart or standard logarithmic chart, new visual field defect, or color defect secondary to optic nerve involvement within the last 6 months.
- Corneal injury not relieved by medical management.
- Improvement in CAS of e 2 points within 1 month prior to screening or between screening and baseline.
- Decrease in proptosis of e 2 mm within 1 month prior to screening or between screening and baseline.
- Previous orbital irradiation or surgery for TED.

... and 18 more (see full listing online)

## Locations (1 total)

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Shanghai Ninth People's hospital, Shanghai Jiaotong University School of Medication, Shanghai, Shanghai Municipality, China

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<https://clinicaltrials.gov/study/NCT06569758>

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