

MHB018A Treatment in Patients With Active Thyroid Eye Disease

NCT06989918

Status	RECRUITING
Phase	Phase 3
Sponsor	Minghui Pharmaceutical (Hangzhou) Ltd
Enrollment	108 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects voluntarily participating in the study and signing the informed consent form;
- Aged 18-75 years (inclusive), of any gender;
- Clinical diagnosis of active Thyroid Eye Disease (TED). The Clinical Activity Score (CAS) of the study eye/target eye at screening and baseline must be e3 points (7-point scale).
- Subjects with a clinical diagnosis of moderate to severe TED at screening and baseline.
- Does not require immediate surgical ophthalmological intervention, and no corrective surgery/orbital radiotherapy is planned during the study.

... and 4 more (see full listing online)

Exclusion (23)

- Decreased best corrected visual acuity due to optic neuropathy as defined by a decrease in vision within the last 6 months of two lines of Snellen chart, new visual field defect or color defect secondary to optic nerve involvement.
- Corneal decompensation unresponsive to medical management.
- Decrease in CAS of e 2 points or decrease in proptosis of e 2 mm between screening and baseline.
- Free thyroxine (FT4) and free triiodothyronine (FT3) levels \<50% above or below the normal reference range at screening.
- Subjects who have previously received orbital radiotherapy or ophthalmic surgery for TED.

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

Locations (1 total)

Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai Municipality, China