

Clinical Study on the Efficacy and Safety of TNTL in the Treatment of Non-proliferative Diabetic Retinopathy

NCT06817265

Status	RECRUITING
Phase	Phase 3
Sponsor	Beletalent (Zhuhai) Pharmaceutical Co., Ltd
Enrollment	360 participants

Key Eligibility Criteria

Inclusion (6)

- Age range of 18 to 75 years old (including boundary values);
 - Conform to the diagnosis of type 2 diabetes and diabetes retinopathy. diabetes retinopathy is classified as NPDR and mild and moderate patients;
 - Patients with the best corrected visual acuity (BCVA) of the target eye is e 34 points (ETDRS visual acuity chart, visual acuity equivalent to a score of 20/200, decimal 0.1);
 - Patients who meet the syndrome differentiation criteria of Yin deficiency, internal heat, and eye meridian stasis in traditional Chinese medicine;
 - During the screening period, glycated hemoglobin (HbA1c) should be d 8.5%;
- ... and 1 more (see full listing online)

Exclusion (21)

- Patients with no light perception in one eye;
 - Patients with macular edema who require anti Vascular Endothelial Growth Factor(VEGF) treatment;
 - People with other eye diseases, such as retinal artery or vein occlusion, non diabetes retinopathy, retinal detachment, uveitis, glaucoma, corneal ulcer, cataract affecting fundus examination, optic neuropathy and high myopia with fundus changes;
 - Patients with acute complications of diabetes (such as diabetes ketoacidosis, hyperglycemia hyperosmolality syndrome, diabetes lactic acidosis, etc.) within one year before the screening period;
 - People with other eye related complications of diabetes, such as iris neovascularization, angle neovascularization, and retinal neovascularization;
- ... and 16 more (see full listing online)

Locations (30 total)

Xuancheng People's Hospital, Xuancheng, Anhui, China
Beijing Chaoyang Hospital, Beijing, Beijing Municipality, China
The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, Guangdong, China
... and 27 more locations

<https://clinicaltrials.gov/study/NCT06817265>

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