

Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Tenzeligliptin Monotherapy in Chinese Patients with Type 2 Diabetes Mellitus Inadequately Controlled With Diet and Exercise

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- This multicenter, randomized, double-blind, placebo-controlled, parallel-group study, carried out at 42 sites, enrolled type 2 diabetes patients with glycosylated hemoglobin 7.0 to <10.0% and fasting blood glucose <270 mg/dL.
- Patients were randomly assigned to treatment with 20 mg teneligliptin or a placebo (n = 127, each) administered orally once daily before breakfast for 24 weeks.
- Change in glycosylated hemoglobin & fasting blood glucose from baseline to week 24 was -0.95% & -21.9 mg/dL with teneligliptin versus -0.14% & -1.4 mg/dL with a placebo respectively.

At 24 weeks, teneligliptin was generally well tolerated and effective in Chinese patients with type 2 diabetes mellitus inadequately controlled with diet and exercise.