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Efficacy and safety of Imeglimin IR 1000 mg in inadequately controlled type 2 diabetes mellitus: A phase III, randomized, double blind study in India

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Objectives: To evaluate the efficacy, safety, and tolerability of imeglimin hydrochloride 1000 mg tablets in participants with T2DM inadequately controlled with diet and exercise.

Methods: A phase III, randomized, double-blind, placebo-controlled, comparative, parallel-group, multicentric clinical study conducted in India between February 2022 and June 2022, lasting for 16 weeks (CTRI/2022/02/040348).

The study involved participants aged 18-65 years with T2DM who were treatment-naive and had inadequately controlled glycemic levels (HbA1c levels of >7.0% to ≤8.5%) despite at least three months of diet and exercise therapy before screening.

Participants were randomized to receive either imeglimin hydrochloride tablets 1000 mg (test drug) or placebo in a 2:1 ratio.

Demographics data, mean change in HbA1c, fasting plasma glucose (FPG) and 2-hour postprandial glucose (PPG) from baseline to week 16 were evaluated.

Of the 216 randomized participants, 205 completed the study, with 140 receiving imeglimin and 65 receiving placebo.

The mean (SD) age of participants was 46.52 (10.16) years in the imeglimin group and 44.83 (10.56) years in the placebo group.

The least square mean (LSM) change in HbA1c from baseline to week 16 was -0.73% in the imeglimin group and 0.13% in the placebo group, with a difference of -0.86% (95% confidence interval [CI]: -0.93, -0.79; P<0.0001)

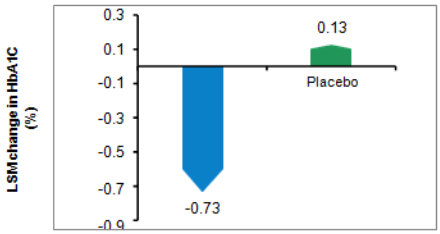

Figure 1: Mean change in HbA1c from baseline to week 16

CI, Δ (95% CI): -0.86 (-0.93 to -0.79); P<0.0001 confidence interval; FPG, fasting plasma glucose; LSM, least square mean; PPG, postprandial glucose

Biography

Prashant Kumthekar completed his master's in pharmacology at the age of 25 from Dr. M.G.R Medical College University in Chennai, India. He currently heads the clinical research department at Exemed Pharmaceuticals in India and brings over 14 years of experience in clinical research. His dedication to all aspects of clinical studies is truly exceptional, as he approaches each task with a unique blend of care and enthusiasm. His remarkable energy and commitment to tackling projects are commendable and vital for success in the clinical research field. His ability to assess and understand the safety profiles of medicinal products showcases his extensive training and expertise. It has been a privilege to collaborate with someone so knowledgeable, reliable, and dedicated to advancing healthcare standards. He is undoubtedly an invaluable asset to any team or organization.

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