Clinical Trial Report: Evaluation of MET-200 for Improving Insulin Sensitivity and Metabolic Control

Introduction:
This clinical trial assesses the effectiveness of MET-200, an innovative metabolic enhancer, in improving insulin sensitivity and overall metabolic control in patients with type 2 diabetes mellitus. Type 2 diabetes is characterized by insulin resistance and inadequate glycemic regulation. MET-200 is a once-daily oral medication designed to enhance insulin sensitivity and improve glucose metabolism. This randomized, controlled trial aims to evaluate MET-200's impact on glycemic control, insulin resistance, and related cardiovascular risk factors.

Methods:
Study Design:
A total of 100 participants with type 2 diabetes mellitus and inadequate glycemic control (HbA1c $\geq$ 7.0%) despite diet and exercise interventions were enrolled in this 24-week, randomized, double-blind, placebo-controlled trial. Participants were randomized in a 1:1 ratio to receive MET-200 (n=50) or a matching placebo (n=50) once daily. All participants continued their existing diet and exercise routines throughout the study.

Inclusion Criteria:
- Age above 18 years
- Diagnosis of type 2 diabetes mellitus
- HbA1c level between 7.0% and 10.0%
- Body Mass Index (BMI) ranging from 25 to 40 kg/m²

Exclusion Criteria:
- History of liver or kidney disease
- Uncontrolled hypertension or cardiovascular events within the past 6 months
- Pregnancy or breastfeeding

Outcome Measures:
The primary outcome measure was the change in insulin sensitivity, assessed by the gold standard euglycemic-hyperinsulinemic clamp technique, from baseline to Week 24. Secondary outcome measures included glycemic control as indicated by HbA1c levels, fasting plasma glucose (FPG) levels, body weight, and lipid profiles. Safety assessments included adverse event monitoring, clinical laboratory tests, and vital sign measurements.

Results:
Primary Outcome:
MET-200 significantly improved insulin sensitivity compared to the placebo group. The mean change in insulin sensitivity, as measured by the clamp technique, was 26.7% in the MET-200 group versus a decrease of -2.3% in the placebo group ($p<0.001$).

Secondary Outcomes:
- HbA1c levels significantly decreased in the MET-200 group, with a mean change of -0.6% from baseline, compared to a decrease of -0.1% in the placebo group ($p<0.01$).
- Fasting plasma glucose levels also showed a significant reduction in the MET-200 group, with a mean of -18.2 mg/dL versus -4.1 mg/dL in the placebo group ($p<0.001$).
- Body weight was significantly reduced in the MET-200 group by a mean of 2.9 kg, while no significant change was observed in the placebo group ($p<0.001$).
- Total cholesterol and LDL cholesterol levels demonstrated a favorable trend toward reduction in the MET-200 group, although the changes were not statistically significant.

Safety:
MET-200 was generally well-tolerated, with a low incidence of mild adverse events. The most common adverse event was temporary dizziness, which occurred in 11 participants receiving MET-200 and resolved without any intervention. No serious drug-related adverse events or changes in vital signs were observed. Clinical laboratory tests did not reveal any safety concerns.

Conclusion:
MET-200 administration resulted in significant improvements in insulin sensitivity, glycemic control, and body weight in type 2 diabetes patients. These findings suggest that MET-200 could be a promising therapeutic option for improving metabolic control in this patient population. The drug's safety profile appears to be acceptable, with manageable mild adverse events.

However, further long-term studies with larger datasets are needed to confirm the sustained efficacy and safety of MET-200 and evaluate its impact on cardiovascular outcomes and health-related quality of life.

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