Safety, Efficacy, and Dose-Response Study of Nutraceutical Supplements

NovoBliss® Research

Background: Obesity increases the risk of several comorbidities, including degenerative arthritis, obstructive sleep apnea, dyslipidemia, hypertension, diabetes mellitus, and coronary artery disease. The test treatment is rich in alpha-amylase inhibitor and has been used for reducing glycemia and calories absorption through preventing or delaying the digestion of complex carbohydrate.

Aims/Objective: To evaluate safety and efficacy in subjects with overweight or mild obesity, to evaluate the degree of significant weight loss by regular intake of test treatments.

Materials/Methods: A clinical study was a randomized, three arm, comparative, double-blinded, placebo-controlled, single-center, dose-response study. A total of 66 subjects ages 18 to 50 years were enrolled, and 62 subjects completed the study. The duration of the study was 6 weeks with total of 4 visits. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with ICH/GCP guidelines. The study was approved by Ethics Committee and registered at Clinical Trial Registry of India and Clinicaltrials.gov.

Results: The test treatment was evaluated for mean percentage change in body weight, reduction in Hip, waist, and thigh circumference, reduction in BMI and reduction in total body fat as well as safety parameters. In this study, there was a statistically significant reduction observed in body weight by 2.1 kg (0.35 kg per week) and 1.94 kg (0.32 kg per week) on Day 45 (visit 4) in treatment groups as compared to 0.13 kg (0.02 kg/week) in placebo. A statistically significant reduction was observed in hip, waist, and thigh circumference with p-value <0.01 in treatment groups as compared to placebo. There was a reduction observed in body fat from baseline to Day 21 and Day 45 in treatments group as compared to no reduction in comparator group. No significant changes were observed in safety parameters after completion of the treatment period. 100% of the study population agreed with the fact that both the test treatments were effective in reducing body weight, BMI, total fat, hip/waist/thigh circumference, hunger feeling and improvement in satiety level, food digestion capacity, and gut health. 100% of the study population were satisfied with both treatments.

Conclusion: As per the Investigator, the test treatment was found to be efficacious in healthy human adult subjects (18 – 50 years) with 100% well-being. After analysis of the various effective parameters, our results clearly revealed that dietary intake of test treatments were found to be significantly effective at reducing body weight, BMI, fat mass, skinfold fat thickness, and waist/hip/thigh circumferences compared to daily intake of placebo in a short time period. No clinically significant changes in blood parameters or adverse events occurred or felt due to the active product during the trial period. The test treatments have the potential to induce weight loss and reduce body fat.