

Study of Long-term Intake of 'Watanabe Active Oyster Tablet': A Safety Evaluation Study in Patients with Type 2 Diabetes

Report from TTC Co., Ltd., Tokyo (participating in this clinical study as the Contact Research Organization)

Subjects and methods:

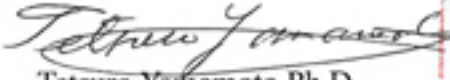
A randomized, placebo-controlled, double-blind, parallel group study was conducted to evaluate the safety and tolerability of a long-term oral dose of 'Watanabe Active Oyster Tablet' in type 2 diabetic patients (HbA1c, >6.5%) who were under treatment with standard anti-diabetic drugs. Thirty diabetic patients (aged 28-75 years), who gave their consent to participate in this study, were randomly assigned to the test tablet (n = 15) or placebo (n = 15) in a daily dose of 12 tablets and the intervention was continued for 12 weeks. All subjects underwent routine health examinations consisting of measurements of anthropometric parameters (height, weight, BMI, blood pressures, heart rate), hematological parameters, and hematochemical parameters, as well as urinalysis, at 4 and 12 weeks intervention. Safety was assessed on the basis of the incidence and severity of intervention-related adverse events reported throughout the 12-week intervention period, and also abnormal changes in hematological and hematochemical laboratory test variables and those in anthropometric parameters.

Results and Conclusions:

The test tablet was well tolerated. None of subjects in both groups reported occurrence of any adverse event during the intervention period. Significant changes from baseline in mean values were seen for serum LDH, serum Fe, MCV and diastolic blood pressure in the test group and for serum total bilirubin, MCV and weight in the placebo group, among which inter-group difference in LDH values reached a significant level. However, all the values with a significant intra-group difference were within the reference interval, showing that any abnormalities in the laboratory tests or anthropometry did not occur throughout the duration of the test tablet intervention.

The data from the present study led us to the conclusion that safety of 'Watanabe Active Oyster Tablet' in a daily dose of 12 tablets given to diabetic patients for a period as long as 12 weeks was confirmed.




Tetsuro Yamamoto Ph.D.
President/CEO

