Confirmation of Safety of "Watanabe Active-type Oyster" in Humans: a Clinical Study with the Regimen of Dosing to Healthy Adults for 12 Weeks

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

Subjects and Methods:

To confirm the safety of an oyster extract-based dietary supplement in a 450 mg-tablet form "Watanabe Active-type Oyster", a clinical study was conducted with 11 healthy adults (5 males and 6 females). Each subject was given 12 tablets of the supplement daily for 12 weeks. All adverse events experienced over the study period were recorded, and several demographic parameters (body weight, systolic/diastolic blood pressures and heart rate), as well as various safety assessment-related laboratory test parameters (hematology, blood biochemistry and urinalysis), were measured at 4, 8 and 12 weeks of intervention.

Results and Conclusions:

Four of the 11 subjects experienced 6 minor adverse events. All of these adverse events were judged by the medical investigator as unrelated to the intervention (or no occurrence of any side effect). There were subjects whose values of some laboratory test parameters at one or more assessment time point(s) deviated from the standard reference interval. However, all of these subject-based abnormal changes were slight in extent and occurred only temporarily. Although statistically significant changes from baseline in mean values of some laboratory test parameters for all subjects were also observed during the intervention, all of them were judged by the medical investigator as minute changes without any clinical relevancy.

These results led us to the conclusion suggesting that long-term intake of "Watanabe Active-type Oyster" in a daily dose used in the present study is well-tolerated and safe in healthy male and female adults.

Manabu Shizume M.D., Ph.D.
Pincipal investigator
Shizume Kinen Clinic

Tetsuro Yamamoto Ph.D.
President/CEO
October 26, 2014