

Safety Evaluation of a Regular Dose and 3- and 5-Fold Increased Doses of ‘Watanabe Active Oyster Tablet’ in Healthy Adults

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

Subjects and Methods:

Safety of a regular dose, along with 3- and 5- fold increased doses, of a tablet-form dietary supplement ‘Watanabe Active Oyster Tablet’ was evaluated in a total of 36 healthy male and female adults. They were randomly assigned to receive the test tablet in a regular dose (12 subjects, 5 males and 7 females; aged 41.2 ± 4.3 years), a 3-fold increased dose (12 subjects, 6 males and 6 females, aged 42.0 ± 2.7 years), or a 5-fold increased dose (12 subjects, 6 males and 6 females; aged 41.1 ± 2.5 years) for 4 weeks. All subjects underwent routine examinations of anthropometrics (height, body weight, Body-Mass Index, blood pressures, and pulse rate), hematology and blood chemistry, and also urinalysis before the start and after the end of 4-week intervention, and at the end of 2-week follow-up. Safety was assessed on the basis of the incidence and severity of test tablet-related adverse events experienced throughout the whole study period, as well as of abnormal changes in anthropometric and laboratory test parameters.

Results and Conclusions:

None of subjects in all the 3 study groups receiving different doses of the test tablet reported occurrence of any adverse event during the intervention and follow-up periods. Anthropometric parameters or laboratory tests did not show any significant abnormalities in the 3 study groups at all the assessment timepoints. Although statistically significant mean changes from baseline in values of several laboratory tests were observed during the study period, all of these changes were limited within the reference interval or the normal range and judged by the Investigator not to be medically problematic.

These results led us to the conclusion that 4-week intake of the test tablet in doses up to 5-fold greater than the regular dose was safe in healthy male and female adults.

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