

Confirmation of Safety of “Watanabe Oyster Drink” 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 liquid form “Watanabe Oyster Drink”, a clinical study was conducted with 11 healthy adults (6 males and 5 females). Each subject was given a bottle (50 ml) 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:

One (female) of the 11 enrolled subjects dropped out the study after the start of intervention due to a withdrawal of participation and the residual 10 subjects (6 males and 4 females) completed the study protocol. Six of the 11 subjects experienced 14 minor adverse events, which were all mild in intensity. However, an adverse event reported by a female subject developing abdominal pain and diarrhea was judged by the medical investigator that the relationship with intervention cannot be ruled out because these symptoms disappeared after discontinuing supplement intake. All other adverse events were mild in intensity and were judged

by the medical investigator as unrelated to the intervention. 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.

Based on these results, we were led to the conclusion suggesting that long-term intake of “Watanabe Oyster Drink” in a daily dose used in the present study is well-tolerated and safe in healthy male and female adults.

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