



Fish collagen peptides for **Lean body mass and physical function**



WELL-BEING

As we age, we naturally lose muscle and become weaker; this can result in physical frailty and is associated with an increased likelihood of falls and impairment in the ability to perform routine activities of daily living. Sarcopenia defines this loss of muscle combined with alterations in physical functions and muscle quality (Evans W. 1997). Among the multimodal approach for muscle mass and physical function management, an optimal diet may be considered.

In this pilot clinical study, **Naticol® has clinically demonstrated an increase in lean body mass over time. Study results also show that physical performance increased significantly more in Naticol® group from baseline (week 0) to end-point (week 24), compared to Placebo group.**



CLINICAL STUDY AFCRO089 - METHODS AND RESULTS

This pilot clinical study was double-blind, randomized, against placebo. It was carried on 28 subjects, mean-aged 62,5 years old, for 24 weeks. As a primary objective, significant change in lean body mass after a daily oral intake of 15g of Naticol® was assessed. Chair stand test and short physical performance battery (SPPB) scores from baseline to week 24 were also evaluated. Safety and tolerance were assessed.

This study was conducted by Atlantia/Hospital of Cork (Rheumatology department, Prof. Ted DINAN, Ireland) and was approved by the local Ethical Committee (CPP). Consent was obtained from each subject before entry in the study.

› **Lean body mass (ITT population) Fig.1**

There was a significant within group effect for Naticol® group in the ITT population where lean body mass significantly increased over time (p=0.025). There was not a significant within group effect for Placebo group.

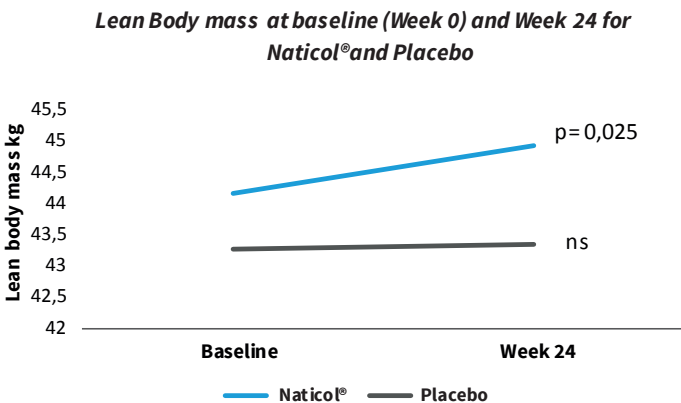


Figure 1- Total lean body mass (ITT); ns: non significant

› **Short physical performance assays (ITT population) Fig.2**

Short physical performance battery tests were used to assess lower extremity function. A 20% trimmed Repeated-measures ANOVA identified a statistically significant interaction in change across time (week 0 and week 24) for Total Score SPPB between Naticol® group and Placebo group, p=0,043. This result indicates that Naticol® group significantly increased in physical performance from baseline to end-point, compared to Placebo group.

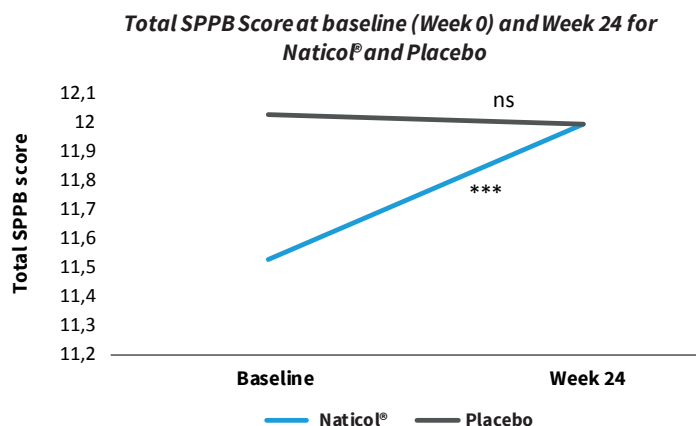


Figure 2 - Total short physical performance battery score at week 0 (baseline) and Week 24 for Naticol® and Placebo, controlling for week 12 (ITT); ns: non significant; *** : p< 0,005

› **Chair stand score (PP population) Fig. 3**

Chair stand test is a measure of lower muscle function. 20% Trimmed Repeated-measures ANOVA identified a significant interaction in change across time (week 0 and week 24) for Chair Stand Test Score between Naticol® group and Placebo group, p =0,011. This result indicates that the subjects who received Naticol® experienced a significant increase in their Chair Stand Test score (from baseline to end point) compared to those who received Placebo (per protocol population).

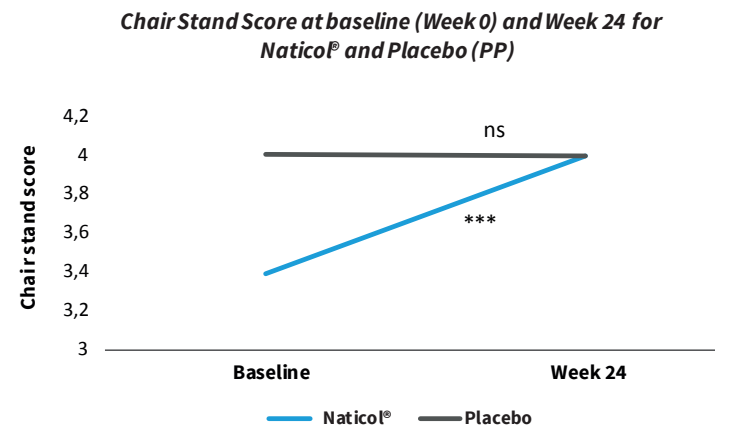


Figure 3 - Chair stand score at week 0 (baseline) and Week 24 for Naticol® and Placebo, controlling for week 12, in the PP population; ns: non significant; ***: p<0,005

› **Conclusion**

The results of oral ingestion of 15 g of Naticol® on a daily basis, up to 24 weeks, clinically showed that regular intake of Naticol® may significantly improve physical function scores. Here, **Naticol® has clinically demonstrated its role as an ingredient in muscle function and mass (lean body mass)**. Naticol® demonstrates globally a good tolerance.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.