SARA program: Preliminary Findings & Implications from SARA-OBS Study and Its Impact on SARA-INT study

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Background

Sarcopenia is a prevalent, progressive muscle disorder in which the onset increases with age and may lead to mobility disability. SARA-OBS, an observational trial, and SARA-INT, an ongoing phase II interventional trial, are part of a clinical program that strives to provide better understanding of the sarcopenia population and to develop a viable treatment option. SARA-OBS included community dwelling sarcopenic adults similar to the target population in SARA-INT that is testing the safety and efficacy of an investigational drug, BIO101.

Findings from SARA-OBS have provided insight on the natural decline in physical functions of the target population and suggest modifications necessary to the current SARA-INT study design.

Objectives

The objective is to better understand the physical performance and the body composition changes in this population within 6 months and use this knowledge to improve the design for the SARA-INT study.

Methods

Older adults $\geq$65 years with a SPPB $\leq$8 and lean body mass based on the FNIH criteria (ALM/BMI < 0.789 in men and 0.512 in women, or ALM <19.75kg in men and <15.02kg in women) were recruited.

Evaluation of the changes in physical performance and body composition from baseline were based on 400m walk test, 6-minute walk test, SPPB, handgrip strength test, stair climb power test and DXA scans.

Results

Preliminary analysis shows a decrease in the gait speed (0.9 vs 0.84; $p<0.0036$), decrease in distance walked (298.84 m vs 279.56 m; $p<.0012$) but no change in the SPPB total score (6.67 vs 6.99; $p<.0915$). A non-significant trend for decreased strength is also detected for the handgrip and the stair climb tests.

These findings led to an amendment in the study design for SARA-INT as follows: 1) increase in the value set for the expected difference between treatment groups, 2) subsequent change in sample

size, 3) change of a key secondary endpoint and 4) introduction of a ‘promising zone’ interim analysis.

Conclusions

SARA-OBS study contributes to better understanding of the at-risk sarcopenic individuals. This knowledge led to improving the design of a comparative clinical trial that will hopefully accelerate the development of BIO101, a medical treatment for age-related sarcopenia.