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Introduction

Sarcopenia (BIO101), purified at 97% of 20 hydrolyzed bone (20E), from the edible plant Stemmacantha carthamoides has shown a true potential to improve muscle quality and function in vitro and in vivo models. BIO101 also accelerates differentiation and enhances myoblast function in skeletal muscle cells. BIO101 was developed as an investigational drug for Age related Sarcopenia including sarcopenic Obesity. Sarcopenia is characterized by the loss of muscle mass and muscle function, which can lead to global muscle functional impairment and physical disability. This poster is focusing on two main studies of the SARA programme. First, SARA-OBS, the ongoing observational study dedicated to characterize the targeted population. Second, SARA-INT, the interventional study with the investigational drug BIO101.

Each of SARA-OBS and SARA-INT study is a 6-month multicenter, clinical trial enrolling community-dwelling persons in Europe and USA aged 65 years and older at risk of mobility disability. The main objective of SARA-INT is to evaluate 2 selected doses of BIO101 in the targeted sarcopenic population.

SARA-OBS, the observational study

Sarcopenia definition used the criteria of the Foundation of the NIH (Studenski et al., 2014) with the risk of mobility disability operationalised using the Short Physical Performance Battery (SPPB; Gurinuk et al., 1994)

- Absolute ALM (< 19.75 kg in men and < 15.02 kg in women) and ALM/BMI (< 0.65 kg in men, < 0.512 kg in women) measured by DEXA
- SPPB ≤ 8

SARA-OBS Clinical study design

- Main objective: characterize the target population in Europe and USA and estimate the prevalence of sarcopenia including sarcopenic obesity in the study sample.
- Primary Endpoint: 400 m walking test gait speed
- Patient reported outcomes (PROs): Short Form Health Survey (SF36).
- Body composition: Gait speed, Grip strength, 6 minutes walk.
- Actimetry; Biomarkers (Mystadist; PINP; IL-6; HscrP; Aldosterine; Renin; Isolated PBMC, etc…)

SARA-OBS preliminary baseline characteristics

- 334 sarcopenic patients reporting loss of physical function and considering at risk of mobility disability will be recruited for the SARA-INT study.
- As for SARA-OBS, the main inclusion criteria follow the Foundation of NIH (Studenski et al., 2014).

SARA-INT preliminary baseline characteristics

- Like for other sarcopenia observational studies, SARA-OBS confirmed recruitment challenges and opportunities in sarcopenia trials when using the NIH criteria (Studenski et al., 2014, ALM/BMI<0.69 in Men and <0.512 in Women) and Absolute ALM <19.75 kg in men and <15.02 kg in women.
- At baseline, approximately 70% of patients presenting were low performers at the FNIH threshold (0.71 ≤ 0.789), but is strictly similar in women.

Conclusions

- Like for other sarcopenia observational studies, SARA-OBS confirmed recruitment challenges and opportunities in sarcopenia trials when using the NIH criteria (Studenski et al., 2014, ALM/BMI<0.69 in Men and <0.512 in Women) and Absolute ALM <19.75 kg in men and <15.02 kg in women.
- At baseline, approximately 70% of patients presenting were low performers at the FNIH threshold (0.71 ≤ 0.789), but is strictly similar in women.

References