

Synbiotic to Attenuate Resorption of the Skeleton

NCT06389539

Status	RECRUITING
Phase	Not Applicable
Sponsor	Hebrew SeniorLife
Enrollment	220 participants

Key Eligibility Criteria

Inclusion (9)

- \. Provided written informed consent.
- \. Stated availability throughout entire study period and willingness to fulfill all details of the protocol.
- \. Age 60 years and above.
- \. DXA-BMD of the hip and spine (T-score) ≥ -2.5 . Women with a BMD T score ≤ -2.5 (i.e. women with low BMD indicating osteoporosis) will also be considered if they have decided not to accept the standard of care use of osteoporosis medications for the entire duration of their participation in the study.
- \. Women with a history of major low-trauma fragility fractures (hip, forearm, humerus, spine) since the age of 50 years will be considered if they are not currently using osteoporosis medications, or if they have decided not to accept the standard of care osteoporosis medications, even if diagnosed with osteoporosis during the screening procedure.

... and 4 more (see full listing online)

Exclusion (38)

- \. BMI greater than 40 kg/m².
- \. Participants consuming dietary supplements (fish oil, probiotics/prebiotics, and fiber) in the prior month, and unwilling to avoid these supplements for the duration of the study.
- \. Participants using osmotic laxatives ≥ 1 per week and unwilling to avoid use for the duration of the study.
- \. Known or suspected allergies to probiotics, rice, edible fruit extract or berries.
- \. Antibiotic use in the past 3 months. Participants placed on an antibiotic after enrollment will be retained.

... and 33 more (see full listing online)

Locations (1 total)

Hebrew SeniorLife, Roslindale, Massachusetts, United States

<https://clinicaltrials.gov/study/NCT06389539>

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