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Robuvit® and muscle mass in seniors

Submission date 04/10/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 11/11/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 11/11/2024	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This research aims to understand how a supplement called Robuvit® affects older adults' muscle strength, physical performance, and overall health. The study will compare the effects of Robuvit® with a dummy treatment over time.

Who can participate?
Generally healthy volunteers aged 65 to 80 years old who lead a sedentary lifestyle, are willing to take the supplement daily and provide blood samples

What does the study involve?
Participants will be randomly assigned to two groups: one will take Robuvit® for six weeks followed by Robuvit® and exercise for an additional twelve weeks, while the other group will take a placebo in the same manner. Throughout the study, participants will undergo physical tests and provide blood samples at the beginning, after six weeks, and after eighteen weeks.

What are the possible benefits and risks of participating?
Benefits may include improved muscle strength and overall health. However, as with any study, there could be potential risks, including side effects from the supplement or the physical tests. Participants will be monitored closely for any adverse effects.

Where is the study run from?
The study is conducted at the Center for Active Aging at the Faculty of Physical Education and Sport, Comenius University in Bratislava, Slovakia.

When is the study starting and how long is it expected to run for?
January 2024 to June 2026

Who Is Funding the Study?
The study is funded by Horphag Research Ltd., the company that produces Robuvit®.

Who Is the Main Contact?
Prof. RNDr. Jana Muchová, PhD, jana.muchova@fmed.uniba.sk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
QR2019-01

Study information

Scientific Title
Effect of French oak wood extract (Robuvit®) on muscle mass in seniors - a human study

Acronym
RobuSar

Study objectives
Supplementation with Robuvit® in seniors, followed by the addition of exercise after six weeks, will enhance muscle strength, physical endurance, and mitochondrial function of skeletal muscles, leading to an increase in muscle mass and improved biochemical parameters related to muscle growth and energy metabolism compared to a placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 22/07/2024, Ethics Committee of Faculty of Medicine Comenius University and University Hospital in Bratislava, Old Town Hospital (Mickiewiczova 13, Bratislava, 81369, Slovakia; +421 2 57290 434; michaela.vaczyova@sm.unb.sk), ref: 54/2024

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy senior volunteers

Interventions
The randomization will be performed by a statistician who will have no contact with the participants. The research team and participants will be unaware of the group assignments and the envelop with assignments will only be opened after the analyses are completed, and the databases are finalized and locked.

In the 1st phase of the study, 60 seniors of both genders aged 65-80 years old, meeting the inclusion criteria, will be randomly assigned to two groups. In the 2nd phase, participants in the Intervention Group will receive daily supplementation with Robuvit® (300 mg/day) for 6 weeks. Participants in the Control Group will receive a placebo under the same conditions.

In the 3rd phase, both groups will undergo a 12-week intervention combining supplementation (Robuvit® or placebo) with exercise. Robuvit® is a standardized extract from the wood of French oak (Quercus robur L.), provided in 100 mg capsules by Horphag Research Ltd. (Geneva, Switzerland). The total daily dose will be 300 mg, divided into two doses: 200 mg in the morning and 100 mg in the evening.

Intervention Type
Supplement

Primary outcome measure
1. Muscle strength measured using isokinetic dynamometry (Biodex System) at baseline, week 6, and week 18. The specific variables assessed will include peak torque and maximum flexion moment of the hamstrings, and peak torque and maximum extension moment of the

quadriceps, along with handgrip strength (using a dynamometer).
2. Physical endurance measured using a submaximal standardized aerobic exercise test on a cycle ergometer (direct measurement of oxygen consumption, VO_2 max) at baseline, week 6, and week 18
3. Body composition (muscle and fat mass) measured using bioelectrical impedance (InBody 720) at baseline, week 6, and week 18, alongside anthropometric parameters (height, weight, waist, and hip circumference)

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline, week 6, and week 18:
1. Resting metabolic rate measured using indirect calorimetry
2. Muscle growth and protein synthesis regulators (myostatin, IGF-1, P3NP, BDNF) measured using serum assays
3. Markers of inflammation (Nrf2, IL-1β, IL-6, TNFα) measured using qRT-PCR (RNA isolated from blood samples)
4. Serum urolithins measured using liquid chromatography-mass spectrometry (LC-MS) for verification of Robuvit intake
5. Creatinine, urea, testosterone, glucose, and growth hormone (GH) levels measured using standard blood assays
6. Mitochondrial respiration measured using an O2k-Respirometer (Oroboros Instruments, Austria), respiratory function of liver mitochondria measured at 30°C using an amperometric measurement of oxygen consumption on an oxygraph Gilson 5/6 H (USA) equipped with a Clark-type oxygen electrode, and CoQ levels measured using a high-performance liquid chromatography (HPLC) method with spectrophotometric detection

Overall study start date
15/01/2024

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Volunteers aged between 65 and 80 years
2. Volunteers with a body mass index (BMI) of less than 35 kg/m^2
3. Volunteers leading a sedentary lifestyle, without symptoms of depression, and with typical dietary habits
4. Volunteers willing to undergo testing for body composition, physical strength, and endurance
5. Volunteers willing to take Robuvit® or placebo daily and provide blood samples
6. Volunteers who are willing to sign an informed consent form

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
65 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Aged <65 years and >80 years old
2. Body mass index (BMI) greater than 35 kg/m²
3. Acute myocardial infarction (MI) or shortly after MI
4. Chronic inflammatory diseases (e.g., rheumatoid arthritis)
5. Unable or unwilling to sign the informed consent form
6. Unable or unwilling to provide biological samples as needed
7. Neurodegenerative and cardiovascular diseases (congestive chronic heart failure, severe or symptomatic aortic stenosis, unstable angina pectoris, untreated arterial hypertension, cardiac arrhythmias), with acute or terminal illnesses including current (treated or untreated) oncological diseases, and those with type 1 or type 2 diabetes mellitus
8. Have undergone surgery/completed chemotherapy/radiotherapy within the last 12 months
9. A history of recent fractures with functional impairment; inability to commit to the study and its requirements

Date of first enrolment
04/11/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Slovakia

Study participating centre
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Faculty of Medicine, Comenius University
Sasinkova 2
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Study participating centre
Center for Active Aging at the Faculty of Physical Education and Sport, Comenius University
Nábrežie armádneho generála Ludvíka Svobodu 9
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Sponsor information

Organisation
Horphag Research (Switzerland)

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Sponsor type
Industry

Website
https://www.robuvit.com/

ROR
https://ror.org/003n34405

Funder(s)

Funder type
Industry

Funder Name
Horphag Research

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Jana Muchova, jana.muchova@fmed.uniba.sk

IPD sharing plan summary

Available on request