ISRCTN47159002 https://doi.org/10.1186/ISRCTN47159002

The effect of Urolithin A (Mitopure®) supplementation on muscle strength in healthy middle-aged adults

Submission date 21/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/10/2025	**Overall study status** Ongoing	
Last Edited 13/01/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This is a randomised, double-blind, placebo-controlled, parallel study to assess the effects of Urolithin A (Mitopure®) supplementation on muscle strength and performance in healthy middle-aged adults. Participants will be randomized to consume Mitopure® (500 mg), Mitopure® (1000 mg), or placebo once daily for 6 months.

Who can participate?
Healthy males and females age 40-65 years.

What does the study involve?
Eligible participants will consume one dose of their randomly assigned food supplement (Mitopure® 500 mg, Mitopure® 1000 mg, or placebo) every day while maintaining their habitual diet and physical activity for 6 months. Measurements of muscle strength, health, and performance will be collected at baseline (before first dose) and after four and six months of supplementation.

What are the possible benefits and risks of participating?
Participation in this study offers no direct benefits to the participants. The study poses negligible risk to participants. The food supplement Mitopure® (Urolithin A) has been established in the market and thoroughly researched for its safety. Participants will be asked to undergo blood sample collection (which might cause pain from the needle going through the skin, bruising, clots under the skin, light-headedness, possible fainting, and, rarely, infection), Dual-Energy X-ray Absorptiometry scans (a non-invasive scan that measures body composition with a very low exposure to radiation. This radiation dose is considered safe to give to humans many times), and fitness testing (which might cause mild muscle soreness and fatigue).

Where is the study run from?
Atlantia Clinical Trials in Cork, Ireland.

When is the study starting and how long is it expected to run for?
Enrolment is planned to begin in December 2025 to April 2027, with the last-participant-last-visit expected in October 2027.

Who is funding the study?
The study is funded by Amazentis SA (Switzerland)

Who is the main contact?
Dr Brad Currier (bcurrier@timeline.com)

Contact information

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Public, Scientific

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Additional identifiers

Protocol serial number
Nil known

Study information

Scientific Title
A confirmatory, randomised, double-blind, placebo-controlled, parallel study to assess the effects of a dietary supplement containing Urolithin A (Mitopure®) on muscle strength and performance in healthy middle-aged adults

Acronym
AFCRO-197 (ATLAS 2.0)

Study objectives
The purpose of this study is to determine the impact of Urolithin A (Mitopure®) supplementation on muscle strength and performance in healthy middle-aged adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/09/2025, Salus IRB (2111 W Braker Ln #100, Austin, TX 78758, United States, Austin, 78758, United States of America; +1 (512) 380-1244; salus@salusirb.com), ref: AFCRO-197

Study design
Interventional randomized double-blind placebo-controlled parallel single-centre study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Muscle strength in healthy middle-aged adults.

Interventions
Participants will be randomized with a list generated by a statistician not involved in the conduct of the study to consume a daily dose of either:
1. Mitopure (Urolithin A dose: 500 mg), or
2. Mitopure (Urolithin A dose: 1000 mg), or
3. Placebo (Urolithin A dose: 0 mg)

For all three study arms, the intervention duration is 6 months (24 weeks), and measurements are performed at baseline (week 0), 4 months (week 16), and 6 months (week 24).

Intervention Type
Other

Primary outcome(s)
Maximum isokinetic knee flexion strength will be measured by Biodex dynamometry (unit: Nm) at baseline and 6 months.

Key secondary outcome(s))

1. Maximum isokinetic knee flexion strength will be measured by Biodex dynamometry (unit: Nm) at baseline and 4 months.
2. Maximum isokinetic knee extension strength will be measured by Biodex dynamometry (unit: Nm) at baseline, 4, and 6 months.
3. Maximum isometric knee flexion strength will be measured by Biodex dynamometry (unit: Nm) at baseline, 4, and 6 months.
4. Maximum isometric knee extension strength will be measured by Biodex dynamometry (unit: Nm) at baseline, 4, and 6 months.
5. Maximum shoulder flexion strength will be measured by Biodex dynamometry (unit: Nm) at baseline, 4, and 6 months.
6. Maximum shoulder extension strength will be measured by Biodex dynamometry (unit: Nm) at baseline, 4, and 6 months.
7. Body composition (lean mass) will be measured by dual-energy X-ray absorptiometry (unit: kg) at baseline, 4, and 6 months.
8. Physical performance (vertical jump) will be measured by maximum vertical jump height (unit: cm) at baseline, 4, and 6 months.

Other Pre-Specified (Tertiary) Outcome Measures
9. Cardiovascular fitness (VO2max) will be measured by a graded exercise test (unit: mL/kg/min) at baseline, 4, and 6 months.
10. Physical capacity (time to exhaustion) will be measured by time to exhaustion during the graded exercise test (unit: minutes) at baseline, 4, and 6 months.
11. Physical capacity (maximum cycling distance) will be measured by maximum cycling distance during the graded exercise test (unit: meters) at baseline, 4, and 6 months.
12. Physical performance (30-second chair stand) will be measured by the 30-second chair stand test (unit: repetitions) at baseline, 4, and 6 months.
13. Physical performance (6-minute walk test) will be measured by the 6-minute walk test (unit: meters) at baseline, 4, and 6 months.
14. Physical performance (timed up-and-go) will be measured by the timed up-and-go test (unit: seconds) at baseline, 4, and 6 months.
15. Blood acylcarnitine level will be measured using blood sample analysis at baseline and 6 months.
16. Blood inflammatory markers will be measured using blood sample analysis at baseline and 6 months.
17. Plasma Urolithin A level will be measured using blood sample analysis at baseline and 6 months.
18. Habitual dietary intake will be measured by 3-day diet diary at baseline, 4, and 6 months.
19. Habitual physical activity will be measured by the International Physical Activity Questionnaire at baseline, 4, and 6 months.
20. Daily fatigue will be measured by FACIT-Fatigue questionnaire at baseline, 4, and 6 months.
21. Safety (adverse events) will be monitored by clinical safety reporting at baseline throughout the trial to 6 months.

Completion date

31/10/2027

Eligibility

Key inclusion criteria

1. Be able to give written informed consent
2. Be between 40 to 65 years of age, inclusive
3. Has a BMI between 25.0 and 34.9 kg/m²
4. Low physical activity levels as assessed by the International Physical Activity Questionnaire (IPAQ)
5. Participants with low VO2 peak (defined as <35 mL/kg/min via the ergometer prior to baseline)
6. Willing to avoid exercising 48 hours prior to study visits and maintain low physical activity status for the duration of the study
7. Willing to avoid caffeine and other stimulants (e.g., energy drinks) 12 hours before exercise as per study guidelines
8. Willing to consume the Study Product daily for the duration of the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants who are pregnant or wish to become pregnant during the study or who are lactating and/or currently breastfeeding
2. Participants currently of biological childbearing potential, but not using a continuous effective method of contraception, as outlined below:
2.1 Complete abstinence from intercourse two weeks prior to administration of the Study Product, throughout the clinical study, until the completion of follow-up procedures or for two weeks following discontinuation of the Study Product in cases where Participant discontinues the study prematurely
2.2 Has a male sexual partner who is surgically sterilised prior to the Screening Visit and is the only male sexual partner for that Participant
2.3 Sexual partner(s) is/are exclusively female
2.4 Use of acceptable method of contraception, such as a spermicide, mechanical barrier (e.g., male condom, female diaphragm), tubal ligation, or contraceptive pill. The Participant must be using this method for at least one week prior to and one week following the end of the study
2.5 Use of any intrauterine device (IUD) or contraceptive implant. The Participant must have the device inserted at least two weeks prior to the first screening visit, throughout the study, and

two weeks following the end of the study
3. Participants with history of drug and/or alcohol abuse at the time of enrolment (drinks more than nationally recommended units per week: >11 units for women; >17 units for men; alcohol /substance abuse disorder)
4. Participants consuming large quantities of pomegranate juice or walnuts or frequent consumers of raspberries, strawberries or cloudberries (2-week washout)
5. Chronic nicotine use
6. Participants who are unable to swallow capsules
7. Is hypersensitive to or has dietary restrictions for any of the components of the Study Product e.g., gelatine
8. Unstable body weight or recent participation in a weight loss program (within 12 weeks prior to screening)
9. Has any significant acute or chronic coexisting health conditions that would prevent them from fulfilling the study requirements, put the Participant at risk or would confound the interpretation of the study results as judged by the investigator on the basis of medical history and routine laboratory test results. Excluded health conditions include:
9.1 Major illness/surgery in the 12 weeks prior to screening
9.2 Diagnosed cardiovascular disease (NYHA Class III or IV congestive heart failure, atrial fibrillation, uncontrolled arrhythmia, uncontrolled hypertension)
9.3 Diagnosed liver disease (cirrhosis, end stage liver disease)
9.4 Diagnosed kidney disease (stage 3b or 4 chronic kidney disease, or kidney failure)
9.5 Diagnosed gastrointestinal disease (IBS/IBD, diarrhoea, acid reflux)
9.6 Uncontrolled thyroid conditions
9.7 Uncontrolled diabetes
9.8 Metallic implants
9.9 Conditions requiring chemotherapy or immunotherapy
10. Current or recent use of a medication that the investigator believes would interfere with the objectives of the study or pose a safety risk or confound the interpretation of the study results. Prohibited medications include:
10.1 Statins or other medications known to impair mitochondrial function
10.2 Anxiolytics, antidepressants, sedative hypnotics (in the 8 weeks prior to Visit 1)
10.3 Antipsychotics, monoamine oxidase inhibitors (in the 8 weeks prior to Visit 1)
10.4 Oral anti-infectives (antibiotics, antivirals, antifungals) for acute infections (in the 12 weeks prior to Visit 1)
10.5 Proton pump inhibitors (PPIs) (in the 4 weeks prior to Visit 1)
10.6 Corticosteroids (>5 mg per day in the past 4 weeks prior to Visit 1)
10.7 GLP-1 agonists (in the 8 weeks prior to Visit 1)
11. Current or recent (in the past 6 weeks prior to Visit 1) use of prohibited nutritional or non-nutritional supplements that the investigator believes would interfere with the objectives of the study or pose a safety risk or confound the interpretation of the study results. Prohibited supplements include:
11.1 Mitopure® containing supplements
11.2 Supplements for muscle strengthening/building or mitochondrial boosting (e.g. high protein, Vitamin B3 [and precursors], L-carnitine, CoQ10, NAD+, resveratrol)
12. Blood donation in the 8 weeks prior to screening
13. Individuals who, in the opinion of the investigator, are considered to be poor attendees or unlikely for any reason to be able to comply with the study
14. Participants may not be participating in other clinical studies. If the participant has previously taken part in an experimental study (physical or muscle performance), the investigator must ensure sufficient time has elapsed before entry to this study to ensure the integrity of the results

Date of first enrolment
10/12/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
Ireland

Study participating centre
Atlantia Clinical Trials
Heron House, Blackpool Retail Park, Atlantia Clinical Trials, Floor 1, Blackpool
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Sponsor information

Organisation
Amazentis (Switzerland)

ROR
https://ror.org/01at1hy26

Funder(s)

Funder type
Industry

Funder Name
Amazentis

Alternative Name(s)
Amazentis SA

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date