ISRCTN60173424 https://doi.org/10.1186/ISRCTN60173424

The effect of four Mitopure food supplement formulations on the amount of Urolithin A in blood

Submission date 27/10/2025	**Recruitment status** No longer 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** Completed	
Last Edited 29/12/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Mitopure is a food supplement that contains Urolithin A, which is a natural molecule. The purpose of this study is to determine the amount of Urolithin A in blood after consuming four different Mitopure formulations.

Who can participate?
Healthy males and females age 18-45 years.

What does the study involve?
Eligible participants will consume a single dose of one of four randomly assigned Mitopure formulations. A blood sample will be collected before the dose and 1, 4, 6, 8, 12, 24 and 72 hours after the dose (eight total blood samples) to measure the amount of Urolithin A in blood.

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. Mitopure is a food supplement that has been sold in the market and thoroughly researched for its safety and effectiveness. 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).

Where is the study run from?
The study will be run at Lokmanya Medical Research Centre and Hospital in Pune, (India)

When is the study starting and how long is it expected to run for?
November 2025 to March 2026

Who is funding the study?
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

Study information

Scientific Title
Comparative pharmacokinetics of Urolithin A (Mitopure) formulations in healthy adults: a randomized, open-label, single-dose, parallel-arm study

Acronym

MHC/CT/25-26/017

Study objectives
The purpose of this study is to compare the pharmacokinetic profile of four different Urolithin A (Mitopure) formulations.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2025, Institutional Ethics Committee Sangvi Multispeciality Hospital (S. No. 71/1 /2/189, C.S. 2387 Krushna Chowk, Krushna Nagar, New Sangvi, Pune, 411027, India; +91 (0) 8090109797; iecsangvihospital@gmail.com), ref: ECR/1865/Inst/MH/2023

Primary study design
Interventional

Study design
Open-label parallel-arm single-period single-dose single-centre randomized study

Study type(s)
Other

Health condition(s) or problem(s) studied
Bioavailability of four Urolithin A (Mitopure) food supplement formulations in healthy adults

Interventions
Participants will be randomized with a computer-generated list to consume a single oral dose of one nutritional formulation, each providing 500 mg of Urolithin A:
1. Mitopure (Urolithin A) Formulation A (reference group), or
2. Mitopure (Urolithin A) Formulation B, or
3. Mitopure (Urolithin A) Formulation C, or
4. Mitopure (Urolithin A) Formulation D

Intervention Type
Supplement

Primary outcome(s)
1. Maximal plasma concentration (Cmax) of Urolithin A measured using repeated blood samples over 72 hours
2. Exposure to Urolithin A measured using area under the curve (AUC) of Urolithin A plasma concentrations over 72 hours

Key secondary outcome(s)
Adverse events and serious adverse events recorded throughout the study

Completion date
15/03/2026

Eligibility

Key inclusion criteria
1. Healthy male and female participants aged between 18 and 45 years (both inclusive)
2. Non-smoker subject or smoker of not more than five cigarettes a day
3. Body Mass Index (BMI) between 18.5-30 kg/m2 inclusive
4. Trial participants in normal health as determined by personal medical history, clinical examination including vital signs, and clinically acceptable results of laboratory examinations (including serological tests), individual values out of the normal range can be accepted if judged clinically non relevant by the Investigator
5. Normal electrocardiogram (ECG) recording on a 12-lead ECG and/or chest X-ray (PA view) significant at the screening visit or considered not clinically significant (NCS) by investigators
6. A negative alcohol breath test result at housing
7. Trial participant able to communicate effectively, provide voluntary written informed consent and available for the entire study duration
8. Trial participants willing to adhere to the protocol requirements as evidenced by written informed consent approved by the ethics committee
9. Ability to fast for at least 14 hours and consume standard meals
10. Accept to refrain consuming certain foods and supplements at least two weeks before inclusion
11. Female participants must have a negative urine pregnancy test prior to housing
12. Trial participants that can provide adequate evidence of their identity
13. The participants agree to refrain from consuming dietary supplements that could potentially impact either muscle or mitochondrial function or contain Urolithin A, such as resveratrol, pomegranate and ellagitannins, nicotinamide riboside, whey protein, leucine, iso-leucine, l-carnitine, creatinine, coenzyme Q10, vitamin A, niacin, folic acids, vitamin C, vitamin E and probiotic foods and supplements, during the 2 weeks before inclusion and throughout the study
14. Females of childbearing potential agree to use appropriate contraceptive measures like non-hormonal intrauterine devices, barrier methods, and spermicidal agents during the study and 7 days after completion of the study
15. Male agreeing to use appropriate contraceptive measures like the Double Barrier method (Condom), and should not donate sperm, etc during the study and 7 days after completion of the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Total final enrolment

Key exclusion criteria

1. Known hypersensitivity to Urolithin A or related product or any component of intervention, presence or history of drug hypersensitivity, allergic disease or lactose intolerance
2. Any history or presence of clinically significant medical condition, such as, but not limited to, cardiovascular, pulmonary, gastro-intestinal, hepatic, renal, metabolic, hematological, neurologic, psychiatric, systemic or infectious disease, thyroid disease, adrenal dysfunction, or organic intracranial lesion
3. Any treatment which could bring about induction or inhibition of the hepatic microsomal enzyme system within one month of starting the study
4. History or presence of alcoholism or drug abuse
5. History or presence of gastric and/or duodenal ulceration
6. History or presence of cancer
7. Difficulty with donating blood
8. Use of any prescribed medication (including herbal remedies) during the two weeks before the start of the study or OTC medicinal products (including herbal remedies) during the week before study initiation and throughout the study
9. Use of medications such as benzodiazepines, anticonvulsants, or barbiturates for one month before the start of the study and throughout the study
10. Trial participant consumed tobacco/tobacco-containing products, pan or pan masala, gutkha, and masala (containing beetle nut and tobacco) for at least 48 hours before initiation of the study and throughout the study
11. Trial participant consumed caffeine and/or xanthine-containing foods or beverages (i.e., coffee, tea, chocolate, and caffeine-containing sodas, colas, etc) and grapefruit juice and poppy-containing foods for at least 48 hours before initiation of the study and throughout the study
12. Major illness during the 90 days before screening
13. Participation in a drug research study within 90 days of screening
14. Positive screening test result for any one or more of the following: HIV, Hepatitis B, Hepatitis C, and VDRL
15. History or presence of easy bruising or bleeding
16. Abnormal diet pattern for whatever reason (e.g., low sodium, fasting, and high protein diets) during the 4 weeks preceding the study
17. Females of childbearing potential with any one of the following reported and documented on the medical history:
17.1. Postmenopausal with spontaneous amenorrhea for at least one year, or
17.2. Bilateral oophorectomy with or without a hysterectomy and an absence of bleeding for at least 6 months, or
17.3. Total hysterectomy and an absence of bleeding for at least 3 months
17.4. Female volunteers who have used implanted or injected hormonal contraceptives anytime during the 6 months prior to study or used hormonal contraceptives within 7 days before dosing
18. Pregnant women and nursing mothers
19. Male and females of childbearing potential unwilling to employ appropriate and reliable method of contraception like non-hormonal intrauterine devices, barrier methods, and spermicidal agents, double barrier method (condom) during the study till 7 days after the completion of the study
20. Male volunteers willing to donate sperm during the study till 7 days after the completion of the study
21. Allergy to peanuts, nuts, pea, or gum guar

Date of first enrolment

03/11/2025

Date of final enrolment
28/11/2025

Locations

Countries of recruitment
India

Study participating centre
Lokmanya Medical Research Centre and Hospital
Office Number 813-816 Sai Millenium
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Sponsor information

Organisation
Amazentis (Switzerland)

ROR
https://ror.org/01at1hy26

Funder(s)

Funder type
Industry

Funder Name
Amazentis

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date