

Metabolism of components from a natural French oak wood extract (Robuvit®) in healthy volunteers

Submission date 03/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Robuvit® is a standardized extract from French oak wood, containing at least 40% polyphenols, mainly ellagitannins. It offers benefits like improved vitality, stress reduction, muscle mass gain, and enhanced mood, all linked to urolithins - active metabolites produced by the gut microbiome (bacteria). The well-known urolithin A has anti-inflammatory, antioxidant, and mitophagy-promoting effects, but its behavior in the body is not well understood. Since ellagitannins are found in common foods like fruits and nuts, it's essential to investigate how urolithins are absorbed and retained. To explore their effects after ellagitannin intake, researchers will conduct a human study analyzing metabolite concentration in blood and saliva after volunteers take Robuvit®.

Who can participate?

Healthy adults (male/female) aged 18 to 65 years

What does the study involve?

The study will be conducted in three phases. In Phase 1, the researchers will identify suitable candidates who produce urolithins after taking a 500 mg dose of Robuvit®. Participants will be asked to provide blood and saliva samples after 24 hours. Those who cannot produce urolithins will be excluded from the study.

In Phase 2 participants will first undergo a 7-day washout period, during which they must avoid foods containing ellagitannins to ensure that no urolithins remain in their system. After this period, 20-25 urolithin-producing participants will take a 500 mg dose of Robuvit®, followed by 1.5 g of blue food dye mixed into plain yoghurt 1 hour later. The time it takes for the blue dye to appear in their stool will indicate gut transit time. Serum and saliva samples will be collected at various timepoints: 0, 6, 8, 10, 12, 24, 30, 48, 54, 72, and 78 hours. After this phase, participants will have three rest days without any sampling.

In Phase 3 participants will receive a daily dose of 300 mg of Robuvit® for four consecutive days. Saliva samples will be collected according to the same schedule as in Phase 2. Blood samples will be taken at the following timepoints: 0, 6, 10, 24, 30, 48, 54, 72, and 78 hours.

What are the possible benefits and risks of participating?
Robuvit® is a natural standardized extract from French oak that positively influences vitality, activity, stress, muscle mass gain, and mood. There are no known risks to participants.

Where is the study run from?
Comenius University (Slovakia)

When is the study starting and how long is it expected to run for?
January 2024 to December 2025

Who is funding the study?
Horphag Research Ltd (Switzerland)

Who is the main contact?
RNDr. Paduchová Zuzana, PhD, zuzana.paduchova@fmed.uniba.sk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

QR2024-01

Study information

Scientific Title

Single intake and steady-state kinetics of ellagitannin metabolites after intake of French oak wood extract (Robuvit®) in serum and saliva – a human study

Acronym

RobuFarm

Study objectives

The goal of this study is to acquire reliable kinetic profiles for urolithins and their glucuronides in serum and saliva after a single intake of Robuvit® and under steady-state conditions.

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, 81369, Bratislava, 81369, Slovakia; +421 (0)2 57290 434; michaela.vaczyova@sm.unb.sk), ref: 53/2024

Study design

Prospective interventional study

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

In the 1st and 2nd phases of the study, healthy volunteers will ingest a single dose of Robuvit (500 mg) and provide blood and saliva samples. In the 3rd phase, volunteers will take a daily dose of 300 mg of Robuvit for 4 days. Robuvit is a standardized extract from the wood of the French oak, prepared in 100 mg capsules by Horphag Research Ltd. (Geneva, Switzerland).

Intervention Type

Supplement

Primary outcome(s)

Urolithins kinetics after intake of a single dose of Robuvit® and under steady-state conditions analysed with a liquid chromatography system with a triple quadrupole mass spectrometer detector (LC-MS). The times of serum and saliva sampling in phase 2 will be at $t = 0, 6, 8, 10, 12, 24, 30, 48, 54, 72$ and 78 hours. If the blue gut transit time indicator is not detected in stool after 4 days, the measurement period may be extended by one day (to 96 or 102 hours). In phase 3, saliva sampling will be conducted as in phase 2, while serum sampling will be limited to time points $t = 0, 6, 10, 24, 30, 48, 54, 72,$ and 78 hours.

Key secondary outcome(s)

1. Correlation analysis: The kinetic profiles of urolithins in serum and saliva measured using LC-MS at different timepoints (t = 0, 6, 8, 10, 12, 24, 30, 48, 54, 72 and 78 hours), and gut transit time assessed by monitoring the presence of blue color in stool after ingesting a blue food dye as a visual marker 1 hour after consuming Robuvit® (individually from hours to days)
2. The levels of urolithins in saliva and blood serum compartments measured by LC-MS at 24 hours after a single dose of Robuvit® to assess the suitability of using saliva for metabotype screening

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Healthy males/females between the age of 18-65 years
2. Will to adhere to dietary limitations during conduction
3. Signed informed consent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

60 years

Sex

All

Total final enrolment

35

Key exclusion criteria

1. Severe/uncontrolled diseases of infectious diseases (e.g., hepatitis)
2. Volunteer cannot take or refuses to take Robuvit® for any reason
3. Age under 18 or over 65 years
4. Volunteer belongs to urolithin-nonproducing metabotype
5. Intake of antibiotics within 4 weeks prior to or during the study

Date of first enrolment

15/10/2024

Date of final enrolment

30/11/2024

Locations

Countries of recruitment

Slovakia

Study participating centre**Comenius University Bratislava**

Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry

Faculty of Medicine

Sasinkova 2

Bratislava

Slovakia

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Sponsor information

Organisation

Horphag Research (Switzerland)

ROR

<https://ror.org/003n34405>

Funder(s)

Funder type

Industry

Funder Name

Horphag Research

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Zuzana Paduchova (zuzana.paduchova@fmed.uniba.sk)

IPD sharing plan summary

Available on request