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Effect of a beetroot-based supplement on nitric oxide levels and inflammation markers in amateur triathletes

Submission date 19/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/03/2026	**Overall study status** Completed	
Last Edited 20/03/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Effect of NOBEET supplementation on reactive oxygen species, pathway of the nitric oxide and markers of inflammation: a randomized, cross-over pilot study

Acronym
GS/01

Study objectives
The primary objective of this pilot study is to assess the effects of NOBEET juice supplementation on parameters of oxidative stress (i.e. ROS), in male subjects practicing non-professional triathlon.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/04/2024, National Ethics Committee for Experimentation by Public Research Institutions (EPR) and Other National Public Institutions (Viale Regina Elena 299 Partita I.V.A. 03657731000 C.F. 80211730587, Roma, 00161, Italy; +39 (0)6 4990 4022; segreteria.comitatoetico@iss.it), ref: 0018156

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Non-professional triathlon

Interventions
This will be an open-label, prospective, randomized, crossover pilot study on effects of NOBEET juice supplementation on markers of oxidative stress and inflammation in male subjects practicing non-competitive triathlon. Four visits in total will be performed. Eligible subjects will perform a first visit (Visit 1, Day 1), during which the subject will be given a wearable device (Actigraph) with the aim to record his physical activity. During this Visit 1, the subjects will be randomized into two sequences: sequence A (which consists of period 1 with active treatment of NOBEET and period 2 with no treatment) and sequence B (which consists of period 1 with no treatment and period 2 with active treatment). Visit 2 (Day 7) will be performed at the end of period 1, which lasts 7 days. A wash-out of 15 days will elapse between period 1 and period 2,

which will start at Visit 3 (Day 22). The final visit (Visit 4, Day 28) will be performed at the end of period 2. Visits will be preferably arranged in the morning. However, all visits will be performed at the same time of the day (± 1 hour) in each individual subject.

The product of the study is NOBEET (Gensan): NOBEET is a dietary supplement containing an extract of red beet (Trubeet), L-citrulline and L-arginine, which acts by promoting a natural vasodilation. The product is commercialized in the Italian market.
The investigational product will be administered once daily (preferably in the morning and at the same hour each day) for 7 days. The recommended dose, according to the product technical data sheet, will be 10 grams of powder diluted in 100 ml of water in subjects weighing up to 80 kg, 20 grams of powder diluted in 200 ml of water in subjects weighing between 80 kg and 90 kg, and 30 grams of powder diluted in 300 ml of water in subjects weighing more than 90 kg. However, the dose of 10 grams may be diluted in a volume of more than 100 ml of water in order to obtain a more homogeneous solution and to reduce the foam that may originate from dilution. A measuring cup will be used to obtain the appropriate dose for each subject.

Intervention Type
Supplement

Primary outcome(s)
1. The reactive oxygen species (ROS) hydrogen peroxide (H2O2) and superoxide anion radical (O2·–) measured using electronic paramagnetic resonance (EPR) at following 7 days of administration of the product under study (Visit 2: Day 7, and Visit 4: Day 28)

Key secondary outcome(s))
1. Oxidative stress, i.e. the ROS H2O2 and O2·–, as measured by means of EPR at the end of the 15-day washout period (Visit 3: Day 22)
2. Parameters of the NO pathway (i.e., blood-inducible nitric oxide synthase [iNOS], blood and urinary nitrogen oxides [NOx], blood 3-nitrotyrosine [3-NT], blood peroxynitrite), after about 2 hours from the first administration of the product under study, following the 7 days of administration of the product under study (Visit 2: Day 7, and Visit 4: Day 28), and at the end of the 15-day washout period (Visit 3: Day 22)
3. Markers of lipidic peroxidation (i.e. blood and urinary 8-isoprostane), as measured by means of an assay kit, after about 2 hours from the first administration of the product under study, following the 7 days of administration of the product under study (Visit 2: Day 7, and Visit 4: Day 28), and at the end of the 15-day washout period (Visit 3, Day 22)
4. Inflammatory cytokines (blood and urinary IL-6 and blood IL-10), as measured by means of an assay kit, after about 2 hours from the first administration of the product under study, following the 7 days of administration of the product under study (Visit 2: Day 7 and Visit 4: Day 28), and at the end of the 15-day washout period (Visit 3: Day 22).

Completion date
04/06/2025

Eligibility

Key inclusion criteria
1. Written voluntary informed consent to participate in the study
2. Male subjects aged 30-59 years (inclusive)
3. Subjects practicing non-competitive triathlon (competitive triathlon may have been practiced in the past up to the age of 20 years)

4. Subjects regularly performing weekly training for at least 300 minutes
5. Subjects with good physical health as determined by medical and surgical history, physical examination
6. Subjects having received a still valid medical certification for suitability to practice agonistic sports
7. Normal blood pressure (systolic blood pressure [SBP] ≥90, ≤140 mmHg; diastolic blood pressure [DBP] ≥50, ≤90 mmHg) measured after 5 min rest in supine position
8. A pulse rate at rest of ≥40 and ≤90 beats/min measured after 5 min rest in supine position
9. Subjects able to comprehend the full nature and the purpose of the study, including possible risks and side effects, and able to cooperate with the Investigator and to comply with the requirements of the entire study (including ability to attend all the planned study visits according to the time limits), based on Investigator's judgement

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
30 years

Upper age limit
59 years

Sex
Male

Total final enrolment
10

Key exclusion criteria
1. Subjects having participate in any race in the past 4 weeks
2. Subjects demonstrating excess in xanthine consumption (more than 5 cups or 1 l of coffee or equivalent per day)
3. Subjects having history of alcohol abuse or drug addiction, or more than moderate actual alcohol consumers
4. Current heavy smokers (former heavy smokers have to have stopped smoking at least 6 months before entry into the study).
5. Use of any medication (self-medication or prescription medication) or non-pharmaceutical products (e.g., food supplements) within 14 days before entry in the study (or at least 5 times the respective elimination half-life, whichever is longer) (exception: a single dose of paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs) is permitted, provided that it is not taken in the previous 48 hours)
6. Any vaccination within 4 weeks before entry in the study
7. Subjects with any active physical disease, acute or chronic
8. Subjects with current or history of any allergies or hypersensitivity reactions, especially with cutaneous manifestation, asthma, urticaria or other severe allergic diathesis as well as current hay fever
9. Subjects with any history of hypersensitivity to the product under study or its excipients
10. Subjects with any history of chronic or recurrent metabolic, renal, hepatic, pulmonary,

gastrointestinal, neurological (especially history of epileptic seizures), endocrinological, immunological, psychiatric or cardiovascular disease, or myopathies
11. Subjects with any central nervous system (CNS)-related, neurological or psychiatric ailments, psychological disturbances, mental restrictions
12. Clinically relevant findings in the physical examination or/and in the cardiopulmonary ultrasound performed at the screening visit
13. Blood donation or plasmapheresis within 4 weeks before entry in the study
14. Any participants who are not able / willing to understand the Informed Consent Form to the study based on their own decision
15. Concomitant participation in another study or participation in the evaluation of any investigational drugs/devices during 3 months before this study or previous participation in the present study
16. The participation in the study is also not permitted to employees of the investigational site with direct involvement in the study or in other studies under the direction of that Investigator, as well as family members of the employees or the Investigator

Date of first enrolment
31/10/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Gensan s.r.l.

Funder(s)

Funder type

Funder Name
Gensan s.r.l.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available