ISRCTN19477801 https://doi.org/10.1186/ISRCTN19477801

Evaluation of the efficacy of a food supplement in improving sports performance, recovery and joint wellbeing

Submission date
27/01/2026

Recruitment status
Recruiting

Registration date
04/02/2026

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Clinical Study Protocol
NT0000277/25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in improving sports performance, recovery and joint wellbeing: a randomized, double-blind, parallel-group, placebo-controlled study

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving sports recovery, performance, and joint wellbeing. The secondary objective of this study is to evaluate the efficacy and pleasantness of the product as perceived by the subjects and the safety of use.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/11/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 200045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: IC007A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers who practise sports and with discomfort in the upper limb joints

Interventions
The active intervention is a food supplement containing Verbascum thapsus L. extract (Verbalief), while the placebo intervention contains the same excipients without the active extract.

A restricted randomization list will be generated by an independent technician using the appropriate algorithm (Wei's urn) of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the randomization list generated.

The study will be double-blind, meaning that participants, the Principal Investigator and collaborators are kept masked to product assignment. Both the active and placebo will be supplied in the same packaging with no obvious differences between them. Subjects take the assigned treatment for 28 days ± 2 days as follows: two capsules per day intake after breakfast with water.

Intervention Type
Supplement

Primary outcome(s)
1. Aerobic endurance performance measured using 12-minute Cooper Running/Walking Test (m) at 10 days

2. Muscle stiffness and soreness measured using MyotonPRO device on the lateral quadriceps of both the right and left legs at full rest: oscillation frequency (i.e. tone) (hz), dynamic stiffness (n /m), logarithmic decrement (i.e. elasticity), mechanical stress relaxation time (ms) and perceived muscle soreness (score from 0 to 10). All these measures are taken at 10 days

3. Muscle explosive strength measured using Portable 3D Force Plate: average rate of force development (rfd) (n/s), peak force (n), time to peak force (s), net impulse (n*s), flight time (s) and jump height (cm). All these measures are taken at 10 days

4. Muscle isometric force measured using Isometric dynamometer: peak force (N), average force (N), time to peak force (s) and rate of force development (RFD) (N/s). All these measures are taken at 10 days

5. Joint mobility and flexibility measured using passive range of motion (prom) (°) and perceived joint stiffness (score from 0 to 10) and flexibility evaluated by the physiotherapist or under his supervision at 10 and 28 days

6. Joint discomfort measured using passive range of motion (prom) (°), perceived joint discomfort (score from 0 to 10) and joint wellbeing status (score from 0 to 10) evaluated by the physiotherapist or under his supervision at 10 and 28 days

7. Antioxidant effect measured using capillary blood: derivatives-Reactive Oxygen Metabolites (d-ROMs) (Carratelli Units) marker of oxidative stress at 10 and 28 days

8. Anti-inflammatory effect measured using ELISA kit from blood samples for interleukin-6 (il-6) (pg/ml), interleukin-1β (il-1β) (pg/ml), interleukin-10 (il-10) (pg/ml), interleukin-12 (il-12) (pg/ml), tumor necrosis factor- α (tnf-α) (pg/ml) and hs c-reactive protein (hs-crp) (mg/l) at 10 and 28 days

Key secondary outcome(s))
1. Product acceptability measured using self-evaluation questionnaire (polytomous question with four possible answers) at 28 days

2. Renal tolerability measured using blood analysis to assess creatinine (mg/dL) at 28 days

3. Hepatic tolerability measured using blood analysis to assess Alanine Aminotransferase (ALT) (U/L), Aspartate Aminotransferase (AST) (U/L) and Gamma-Glutamyl Transferase (GGT) (U/L) at 28 days

4. Hematological monitoring measured using blood analysis to assess complete blood count (CBC): red blood cells (106/µl), leukocyte count (103/µl), hemoglobin (g/dl), hematocrit (%), platelets (103/µl) at 28 days

Completion date
17/04/2026

Eligibility

Key inclusion criteria
1. Healthy male and female volunteers
2. Caucasian ethnicity
3. Aged between 18 and 45 years (extremes included)
4. Practice sports*
5. Female subjects not in the menstrual bleeding phase of their cycle during the study visits
6. Normal electrocardiogram (ECG)
7. Discomfort in the upper limb joints (not related to any underlying pathology)**
8. Registered with the National Health Service (NHS)
9. Certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
10. Able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
11. Able to respect the instructions given by the Principal Investigator or designated personnel, as well as able to respect the study constraints and specific requirements
12. Commit not to change their daily routine or lifestyle during the study ***
13. On stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
14. Informed about the test procedures who have signed a consent form and privacy agreement

*40 to 60 minutes of non-competitive training, two to three times per week
**Clinical evaluation of joint wellbeing status from 4 to 8 (extremes included)
***Subjects will keep a diary to ensure that they do not change their exercise and eating habits during the study

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Do not meet the inclusion criteria
2. Smokers
3. Any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal Investigator considers dangerous to the subject or incompatible with the requirements of the study ****
4. Participating or planning to participate in other clinical trials
5. Participated in a similar study without respecting an adequate washout period (at least 1 month)
6. Have food intolerances or food allergies to ingredients of the study product
7. Under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator *****
8. Currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least 1 month)
9. Admitted to a health or social facility
10. Planning a hospitalization during the study
11. Not able to be contacted in case of emergency
12. Deprived of freedom by administrative or legal decision or under guardianship
13. Have or have had a history of alcohol or drug addiction
14. Eating disorders (i.e., bulimia, psychogenic eating disorders, etc)
15. Breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

**** Including musculoskeletal disease, metabolic disease, high blood pressure, asthma, or skeletal neuromuscular injuries
***** Including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Corticosteroids, Chronic pain medications (e.g. Opioid Analgesics), Antidepressants

Date of first enrolment
15/12/2025

Date of final enrolment
13/03/2026

Locations

Countries of recruitment
Italy

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Sponsor information

Organisation
BIONAP S.R.L.

Funder(s)

Funder type

Funder Name
BIONAP S.R.L.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available