ISRCTN86000110 https://doi.org/10.1186/ISRCTN86000110

Evaluation of the efficacy of a food supplement on visual performance in young motocross riders

Submission date 12/11/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/11/2026	**Overall study status** Ongoing	
Last Edited 13/11/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Clinical study protocol
EC_P260000781

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in improving visual performance in young motocross riders: a pilot single-arm, baseline-controlled study (pre–post), single-site

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/10/2026, International Ethics and Integrity Committee (Via per Garbagnate, 61, Lainate, 20045, Italy; +39 3522069745; secretariat@ieicommittee.com), ref: IC0034 A

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy young volunteers who are active motocross riders

Interventions
The study will be a pilot single-arm, baseline-controlled study (pre-post), single-site clinical study. The food supplement containing Mulberry and Verbasco Extract, (Viseoris).

Subjects take the assigned product for 40 days ± 2 days as follows: two capsules daily, one in the morning and one in the evening, with a glass of water.

The following methods are used to measure outcomes. The Pelli–Robson chart is one of the most widely used clinical letter charts for contrast sensitivity. Its design uses large Sloan letters that decrease in contrast rather than size, arranged in groups of three letters, or “triplets.” Successive triplets decrease in contrast, and scoring is based on the faintest triplet read correctly.

A projected Snellen eye chart will be mounted so that its centre is approximately at the subject’s eye level, at a viewing distance of 6 meters, under uniform illumination of at least 480 lux.

The TNO stereotest, during which the subject will be seated comfortably, and the test plates will be presented at the recommended viewing distance, typically approximately 40 cm, under adequate illumination. The plates will be held squarely in front of the subject and will not be tilted or rotated.

The online Human Benchmark platform reaction time measures the time required to click on a box that is initially colored red and suddenly changes to green. The time is measured in milliseconds. The test is performed using a 1200 dpi optical mouse. The internet connection required to perform the test will be fiber-optic, to reduce response latency. Aim trainer. Measures the time required to hit a continuously moving target. The test records the total time needed to hit the target with the cursor 30 consecutive times. This test will also be performed using a fiber-optic internet connection to minimize latency.

The crossbox device will be worn by each rider and will geolocate, via GPS, all movements performed during the test session. Crossbox will be used to measure the following parameters: Lap time: reduction in the average lap time on a standardized circuit; Error rate: reduction in the number of corrections, grip losses, or incorrect trajectories; Maximum speed reached; Speed recorded in a selected reference corner.

Intervention Type
Supplement

Primary outcome(s)
1. Contrast Sensitivity: right eye; left eye; both eyes (Log CS), measured using the Pelli-Robson contrast sensitivity chart at T0 (baseline) , T20 (day 20) and T40 (day 40)

Key secondary outcome(s)
1. Visual Acuity measured using a projected Snellen eye chart test - right eye; Snellen eye chart test - left eye (Snellen fraction) at T0, T20 and T40

2. Stereopsis (seconds of arc) measured using the TNO stereotest at T0, T20 and T40

3. Visuomotor Reaction Time (VMRT) measured using the online Human Benchmark platform reaction time: reaction time (ms); aim trainer (ms) at T0, T20 and T40

4. Motocross performance metrics measured using the Crossbox device: Lap time (mm:ss.ms), error rate (%), maximum speed (Km/h), speed in a reference corner (Km/h), at T0, T20 and T40

5. Efficacy perceived and the pleasantness of the product measured using self-assessment questionnaire (13 questions) at T0 and T40

Completion date
03/02/2027

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Subjects aged between 15 and 22 years (extremes included)
3. Active motocross riders who agree to maintain a stable training load throughout the study period*
4. Subjects with the ability to use a personal computer
5. Subjects registered with National Health Service (NHS)
6. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
7. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
8. Subjects 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
9. Subjects who commit not to change their daily routine or lifestyle during the study
10. Subjects 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
11. Subjects informed about the test procedures who have signed a consent form and privacy agreement.
*Subjects will maintain a weekly diary to record their training activity.

Parents/Guardians of subjects
People who have parental responsibility for the minor must meet specific inclusion and exclusion criteria listed in the sections here below:
Inclusion criteria
1. Parents/Guardians of minors aged over 18 years old
2. Parents/Guardians of the minors certifying the truthfulness of the minor personal data disclosed to the investigator
3. Parents/Guardians of the minors able to understand the language used in the investigation center and the information given by the investigator
4. Parents/Guardians of the minors able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
5. Parents/Guardians of the minors informed about the test procedures who have signed a consent form and privacy agreement
6. Parents/Guardians of the minor’s commitment not to use other similar products on the minor during the study

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
15 Years

Upper age limit
22 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study**
3. Subjects participating or planning to participate in other clinical trials
4. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
5. Subjects that have food intolerances or food allergies to ingredients of the study product
6. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator ***
7. Subjects currently using food supplements and/or products with similar activity to the investigational product, or other supplements/products that may confound the evaluation of study outcomes, or who have not observed an adequate washout period (at least one month) ****
8. Subjects admitted to a health or social facility
9. Subjects planning a hospitalization during the study
10. Subjects not able to be contacted in case of emergency
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects who have or have had a history of alcohol or drug addiction
13. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
14. Subjects breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).
** Including malignancy, severe cardiovascular disease, severe hepatic or renal impairment, neurological or psychiatric disorders, serious infections, autoimmune diseases, ocular diseases, ocular pathology or recent ocular surgery/trauma and any medical condition that may affect alertness, reaction time or visual function or that, in the opinion of the Principal Investigator, may interfere with the study.
*** Including the use of medications or substances known to affect alertness, reaction time or visual function or that, in the opinion of the Principal Investigator, may interfere with the study.
**** Including consumption of berries or other high-anthocyanin foods within 72 hours prior to each study visit.

Parents/Guardians of subjects
People who have parental responsibility for the minor must meet specific inclusion and exclusion criteria listed in the sections here below:
Exclusion criteria
1. Parents/Guardians of minors who do not meet the inclusion criteria
2. Parents/Guardians of the minors who have or have had a history of alcohol or drug addiction
3. Parents/Guardians of the minors deprived of freedom by administrative or legal decision or under guardianship
4. Parents/Guardians of the minors not able to be contacted in case of emergency

Date of first enrolment
07/12/2026

Date of final enrolment
21/12/2026

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Bionap Srl (Italy)

ROR
https://ror.org/02fh97n20

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