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Evaluation of the efficacy of a food supplement in reducing joint discomfort

Submission date	Recruitment status	[ ] Prospectively registered
03/02/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/02/2026	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Additional identifiers

Clinical Study Protocol Number
EC_NT0000372

Study Code_Order
H.E.HU.HV.NJS00.090.00.00_NT0001506-25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in reducing joint discomfort: 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 reducing joint discomfort. The secondary objective of this study is to evaluate the efficacy and pleasantness of the product as perceived by the subjects.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/12/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: Rif IC10 A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy subjects with mild to moderate joint discomfort, overweight and who practise sports.

Interventions
The active product will be tested in two formulations containing different amounts of Sodium Hyaluronate (ExceptionHyal®Jump - one with twice the dose of the other), while the placebo contains the same excipients without the active ingredients.
A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei'surn") 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 generated randomization list: one third of the subjects will be allocated to the first formulation of the active product, one third of the subjects will be allocated to the second formulation of the active product and one third of the subjects will be allocated to a placebo.
The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between them.
Subjects will take the assigned treatment for 28 days ± 2 days as follows: one capsule per day in the morning, with a glass of water, either before or after meals.

Intervention Type
Supplement

Primary outcome(s)
1. Passive Range of Motion (PROM) measured using goniometer (°) at baseline, 10 and 28 days of product use.

2. Active Range of Motion (AROM) measured using goniometer (°) at baseline, 10 and 28 days of product use.

3. Discomfort on palpation measured using Numerical Rating Scale (NRS) from 0 to 10, where 0 indicates the absence of discomfort, and 10 indicates severe discomfort at baseline, 10 and 28 days of product use.

4. Perceived joint discomfort measured using Numerical Rating Scale (NRS), where 0 represents "no discomfort" and 10 indicates the "worst discomfort imaginable" at baseline, 10 and 28 days of product use.

Key secondary outcome(s)
1. Efficacy perceived and the pleasantness of the product measured using self-evaluation questionnaire (polytomous question with four possible answers) at 28 days of product use.

Completion date
24/04/2026

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 25 and 55 years (extremes included)
4. Subjects with mild to moderate joint discomfort (not related to any underlying pathology) *
5. Subjects who are overweight **
6. Subjects who practice sports***

7. Subjects registered with national health service
8. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
9. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
10. 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
11. Subjects who commit not to change their daily routine or lifestyle during the study ****
12. 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
13. Subjects informed about the test procedures who have signed a consent form and privacy agreement
* Discomfort on palpation and perceived joint discomfort from 4 to 8 (extremes included)
** BMI between 25 kg/m² and 29.9 kg/m². According to the World Health Organization (WHO) BMI Classification.
*** 45 to 60 minutes of non-competitive training, 1 to 2 times per week. Participants will avoid excessive strain as instructed by the physiotherapist on the joint causing the greatest discomfort at baseline visit, which will be the joint investigated throughout the study.
**** 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
25 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Female subjects who are postmenopausal
3. Subjects with 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. Subjects participating or planning to participate in other clinical trials
5. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
6. Subjects that have food intolerances or food allergies to ingredients of the study product
7. Subjects under pharmacological treatments that are considered incompatible with the study

requirement by the Principal Investigator ******
8. Subjects who are 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 one month)
9. Subjects admitted to a health or social facility
10. Subjects planning a hospitalization during the study
11. Subjects not able to be contacted in case of emergency
12. Subjects deprived of freedom by administrative or legal decision or under guardianship
13. Subjects who have or have had a history of alcohol or drug addiction
14. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
15. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).
***** Including musculoskeletal disease, skeletal neuromuscular injuries, autoimmune diseases
****** Including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Corticosteroids, Pain medications taken daily or on a regular basis

Date of first enrolment
07/01/2026

Date of final enrolment
06/03/2026

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
ROELMI HPC S.R.L., Via Celeste Milani 24/26 – 21040 Origgio (VA), Italy

Funder(s)

Funder type

Funder Name
ROELMI HPC S.R.L.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available