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Clinical trial evaluating a food supplement for joint and bone support, conducted as a randomized, double-blind, placebo-controlled study in subjects with osteopenia (loss of bone density)

Submission date
16/10/2025

Recruitment status
Recruiting

Registration date
28/10/2025

Overall study status
Ongoing

Last Edited
24/10/2025

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

Background and study aims
Age-related musculoskeletal deterioration is a growing public health concern, with osteopenia, joint stiffness, and reduced mobility significantly impacting quality of life in aging populations, particularly in postmenopausal women.
Nutritional strategies are gaining attention, especially those involving bioactive peptides that can both stimulate bone mineralization and promote extracellular matrix regeneration through collagen and glycosaminoglycan production.
While traditional supplements usually focus on calcium, vitamin D, or collagen, innovative peptide-based formulations aim to improve bone density and joint function at the same time.
Novastyne®Flex, the product under investigation, is a patented peptido-mineral complex developed using a defined sequential peptide-release technology (SEQ-ID™). This technology produces a reproducible profile of amino acids and peptides designed to mimic natural sequences for optimized absorption and multi-target biological activity on bone and joint tissues.
In vitro studies have shown that the complex stimulates osteoblast and chondrocyte activity, increases the expression of growth factors involved in bone and cartilage regeneration, enhances glycosaminoglycan and collagen synthesis.
Overall, these results suggest that Novastyne® Flex may help support bone metabolism, promote cartilage integrity, and contribute to the prevention of osteopenia-related tissue deterioration.
Postmenopausal women aged 50 to 70 with mild osteopenia represent an appropriate target population for clinical studies, as they often experience both bone loss and joint discomfort while generally not requiring pharmacological treatment. This approach may therefore offer a valuable non-drug option for managing age-related musculoskeletal decline and preventing fragility syndromes.

Who can participate?
Healthy female subjects aged between 50 and 70 years, with osteopenia and with mild to moderate joint discomfort

What does the study involve?
Participants are asked to:
- Provide written informed consent prior to any study-related procedure.
- Attend scheduled study visits conducted by the principal investigator or delegate at baseline, and after 1 month, 3 months, 6 months, 9 months, and 12 months.
- Undergo physiotherapy assessments at baseline, and after 1 month and 3 months.
- Undergo DEXA scans of the lumbar spine and femoral neck the day before baseline, and at 6 and 12 months visits.
- Undergo blood tests on the morning after baseline, and after 1, 3, 6, and 12 months visitis
- Complete a self-assessment questionnaire at the final visit.

What are the possible benefits and risks of participating?
Risks associated with the product intake are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the product formula are commonly used in dietary supplements. The potential benefits of using the product include reducing joint discomfort and providing support for the bones.

Where is the study run from?
Nutratech SRL, Rende (CS), Italy

When is the study starting and how long is it expected to run for?
June 2025 to December 2026

Who is funding the study?
NOVACTIVA (France)

Who is the main contact?
Roberta Villa, roberta.villa@complifegroup.com

Contact information

Type(s)
Public, Scientific

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Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
H.E.HU.HV.NJS00.060.00.00_NT0000957/25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement for joint and bone support: a randomized, double-blind, parallel-group, placebo-controlled study in subjects with osteopenia

Acronym
JOBO

Study objectives
The objective of the study is to determine whether a food supplement can positively support joints and bones.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/09/2025, Comitato etico indipendente per le indagini cliniche non farmacologiche (Independent Ethics Committee for Non-Pharmacological Clinical Investigations) (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: Rif. 2025 /15

Study design
Double-blind randomized parallel-group placebo-controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Female postmenopausal subjects with osteopenia and mild to moderate joint discomfort

Interventions
The product under investigation is a patented bioactive and bioavailable peptido-mineral complex. Half of the recruited subjects are randomized to receive the active product, while the other half receive the placebo. A restricted randomization list is generated by an independent technician using the appropriate algorithm (Wey's urn) implemented in PASS 11 software (PASS, LLC, Kaysville, UT, USA) and stored in a secure location. The principal investigator or a designated delegate dispenses the investigational products according to the randomization list. The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. Both the active and placebo products are provided in identical packaging, with no distinguishable differences between them. Subjects take the assigned treatment for 12 months (336 days ± 2 days) as follows: two capsules together once daily, at any time, with or without food.

Intervention Type
Supplement

Primary outcome(s)
1. T-score obtained through DEXA - lumbar spine (g/cm²) at baseline, and after 168 days and 336 days of treatment
2. T-score obtained through DEXA - femoral neck (g/cm²) at baseline, and after 168 days and 336 days of treatment
3. CTX (C-terminal telopeptide of type I collagen) (pg/ml) at baseline, and after 84 days, 168 days and 336 days of treatment
4. P1NP (Procollagen Type I N-Terminal Propeptide) (pg/ml) at baseline, and after 84 days, 168 days and 336 days of treatment
5. Passive range of motion (PROM) (°) at baseline, and after 28 days and 84 days of treatment
6. Active range of motion (AROM) (°) at baseline, and after 28 days and 84 days of treatment
7. Discomfort on palpation (Score from 0 to 10) at baseline, and after 28 days and 84 days of treatment
8. Perceived joint discomfort (Score from 0 to 10) at baseline, and after 28 days and 84 days of treatment

Key secondary outcome(s))
Self-evaluation questionnaire (polytomous question with four possible answers) after 336 days of treatment

Completion date
18/12/2026

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Caucasian ethnicity

3. Postmenopausal
4. Subjects aged between 50 and 70 years (extremes included)
5. Subjects with osteopenia*
6. Subjects with mild to moderate joint discomfort (not related to any underlying pathology) **
7. Subjects registered with National Health Service (NHS)
8. Subjects certifying the truthfulness of the personal data disclosed to the investigator
9. Subjects able to understand the language used in the investigation centre and the information given by the investigator
10. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
11. Commitment not to change the daily routine or lifestyle
12. Stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least two months 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
*At the recruitment, T-score between -1,0 and 2,5 (assessed through DEXA analysis on lumbar spine and femoral neck).
According to the World Health Organization - WHO:
-T-score ≥ -1,0: Normal bone density
-T-score between -1,0 and -2,5: Osteopenia
** At the recruitment, Discomfort on palpation (see paragraph 8.7) and Perceived joint discomfort (see paragraph 8.8) scores from 4 to 8 (extremes included)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
70 years

Sex
Female

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 two months)
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 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 two months)****
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.)
***Musculoskeletal diseases or skeletal neuromuscular injuries (e.g. advanced osteoarthritis; moderate osteoarthritis with an ongoing inflammatory component, significant mobility impairment, or treated with a joint injection within the past two months; recent fractures; neuromuscular disorders affecting mobility),
autoimmune diseases (e.g. active rheumatoid arthritis, systemic lupus erythematosus; ankylosing spondylitis; polymyalgia rheumatica; psoriatic arthritis),
neurological or psychiatric disorders (e.g. multiple sclerosis; Parkinson’s disease; major depression; schizophrenia).
****Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (Occasional use will be tolerated, with a maximum of two tablets per month. Participants will be required to maintain a diary documenting medication use),
systemic corticosteroids,
pain medications taken daily or on a regular basis, anti-osteoporosis treatment,
medications affecting bone or cartilage metabolism (e.g. bisphosphonates, denosumab),
intra-articular injections of hyaluronic acid, triamcinolone, or methylprednisolone within the past two months,
Hormonal Replacement Therapy (e.g. estrogen or estrogen-progestin therapy), parathyroid hormone analogues.

Date of first enrolment
08/09/2025

Date of final enrolment
19/12/2025

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech SRL
Via Francesco Todaro 20/22
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Italy
87036

Sponsor information

Organisation
NOVACTIVA

Funder(s)

Funder type
Industry

Funder Name
Novactiva

Results and Publications

Individual participant data (IPD) sharing plan
Stored in non-publicly available repository.
Published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes