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Effects of a food supplement in women with stress-predominant urinary incontinence

Submission date
17/01/2025

Recruitment status
No longer recruiting

Registration date
21/01/2025

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Urological and Genital 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
Urinary incontinence (UI) is a common condition affecting women worldwide, with pelvic floor muscle training exercises (PFMT) recognized as the first-line treatment for UI. Supplementation with bioactive compounds, such as collagen and magnesium, may enhance the effectiveness of PFMT. This study aims to evaluate the efficacy of combining a food supplement containing collagen and magnesium with PFMT in women experiencing stress, urge, or mixed UI.

Who can participate?
Healthy Caucasian women aged 45 to 70 years with stress, urge or mixed UI

What does the study involve?
Participants in the study were divided into two groups at random for a 6-week study. One group (the active group) received a daily stick pack of a food supplement called Dermoxen® (PelviPlus globally and Urocollagen in China). The other group (the placebo group) received a daily stick pack that looked the same as the supplement but only contained inactive ingredients like isomalt, citric acid, lemon flavoring, sucralose, and silicon dioxide.

The improvement in urinary incontinence was assessed, before and after 6 weeks (W6) of product use, using a questionnaire (QUID) and a clinical assessment of the gynecologist. Quality of life (QoL) was assessed as a secondary endpoint.

What are the possible benefits and risks of participating?
Possible benefits: Improvement of UI and related QoL in women.

Possible risks: Allergic reactions to one or more ingredients contained in the food supplement.

Where is the study run from?
EKUBERG pharma s.u.r.l. (Carpignano Salentino, Italy)

When is the study starting and how long is it expected to run for?
March 2024 to October 2024

Who is funding the study?
EKUBERG pharma s.u.r.l. (Carpignano Salentino, Italy)

Who is the main contact?
Dr Davide Carati, davide.carati@ekubergpharma.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EKU_01-2025

Study information

Scientific Title
Efficacy of a food supplement based on collagen and magnesium in women with stress-predominant urinary incontinence: a double-blind, randomized, clinical trial

Study objectives
Supplementation with a food supplement containing collagen and magnesium in combination with pelvic floor muscle training exercises, can improve the condition of stress, urge, or mixed urinary incontinence in women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2024, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche) (Via XX Settembre 30/4, Genova, 16121, Italy; +39 010 545481; info@studinonfarmacologici.it), ref: NT0000653/24 vers. 01

Study design
Single-center randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Treatment of urinary incontinence and improvement of quality of life

Interventions
This single-center, randomized, double-blind, placebo-controlled trial was conducted over a 6-week follow-up period at the Nutratech S.r.l. facilities (Rende, CS, Italy) between June and September 2024. It consisted of a screening visit, a baseline visit (W0) and a follow-up (W6) visit after 6 weeks of product use. Eligible subjects were enrolled, at baseline by a board-certified gynecologist and randomized to receive the active or the placebo product. After the baseline visit subjects received detailed instruction and training on pelvic floor muscle exercises by a physiotherapist.

After the enrolment subjects were assigned to receive the active or the placebo products in a 1:1 ratio. The active arm (DXP) received (daily) 1 stick pack of a commercially available food supplement (Dermoxen® PelviPlus worldwide and Dermoxen® Urocollagen in the Chinese market, EKUBERG pharma, Carpignano Salentino, Italy) for daily consumption. The placebo arm (PLA) received (daily) 1 stick pack which has the same appearance as the active product and contains isomalt, citric acid, lemon flavoring, sucralose, and silicon dioxide for daily consumption. A restricted randomization list was generated by PASS 11 (version 11.0.8, PASS, LLC, Kaysville, UT, USA) using the “Efron’s biased coin” algorithm. Participants received the food supplement in sealed boxes, each labeled uniquely coded to maintain blinding. The randomization list was securely stored in sequentially numbered, sealed, and opaque envelopes, ensuring that both the investigator and the participants remained unaware of the product assignment.

Participants were instructed to report any adverse events throughout the study. Compliance with the treatment was determined by counting and recording the unused stick packs at the end of the 6-week treatment period, with a compliance threshold defined as ≥ 80%. Participants with

compliance below 80% were excluded from the inten-tion-to-treat (ITT) population due to poor adherence to the treatment regimen.

The Questionnaire for Urinary Incontinence Diagnosis (QUID) is a self-administered, 6-item questionnaire for UI symptoms, proven to be reliable and valid when compared to standard clinical evaluations in outpatient urogynecology settings. The first three items of the questionnaire address symptoms of SUI, while the remaining three focus on UUI symptoms. Possible answers to each item are six frequency-based options (from “none of the time” to “all of the time”) scored on a 6-point scale (from 0 to 5). Scores are calculated additively, yielding separate Stress and Urge scores, each ranging from 0 to 15 points.

Intervention Type
Supplement

Primary outcome measure
1. Improvement in stress urinary incontinence (SUI) and urge urinary incontinence (UUI) symptoms measured using the Questionnaire for Urinary Incontinence Diagnosis (QUID) before and after 6 weeks (W6) of product use
2. The gynecologist's opinion of the product's efficacy measured using a verbal rating scale at the end of the treatment period

Secondary outcome measures
Quality of life (QoL) measured using a QoL questionnaire consisting of 10 items focused on the participant's perception of the urinary incontinence discomforts in the last two weeks. Answers were on an 11-point numerical rating scale (NRS) from 0 (“not at all”) to 10 (“maximum discomfort”) before and after 6 weeks (W6) of product use

Overall study start date
01/03/2024

Completion date
10/10/2024

Eligibility

Key inclusion criteria
1. Healthy Caucasian women aged 45 to 70 years
2. A diagnosis of stress (S) and/or urge (U) urinary incontinence (UI) confirmed by a board-certified gynecologist based on clinical anamnesis and the answers to the Questionnaire for Urinary Incontinence Diagnosis (QUID). The cut-off value was set at ≥ 4 for SUI and ≥ 6 for UUI.

Participant type(s)
Patient, Population

Age group
Mixed

Lower age limit
45 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
56

Total final enrolment
44

Key exclusion criteria
1. A positive medical history of pathologies (acute, chronic, or progressive) or pharmacological treatments (i.e. alpha-adrenergic blockers/stimulants, anticholinergics, calcium channel blockers, psychoactive drugs, misoprostol, opioids, hormone replacement therapy, diuretics) that could potentially interfere with the test product
2. Simultaneous participation in other clinical trials
3. Participation in a similar trial without an adequate washout period
4. Food intolerance or food allergies (including allergies to ingredients of the test product)
5. Concomitant use of food supplements, topical products or procedures to treat UI
6. Prior use of UI-active products or procedures without an adequate washout period
7. History of drug, alcohol, or substance abuse
8. Nutrition and eating disorders (e.g. bulimia, psychogenic eating disorders, etc.)
9. Pregnancy or breastfeeding women
10. Absence of adequate contraceptive measures in women of childbearing age

Date of first enrolment
01/07/2024

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech S.r.l.
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Sponsor information

Organisation
Ekuberg Pharma

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Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
Ekuberg Pharma

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Raw data will be stored on the Nutratech s.r.l. server. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be included in the study report and shared with the study sponsor in a PDF file electronically signed. The raw data will be stored for a minimum period of 10 years on Nutratech s.r.l. servers. In the raw data tables, subjects are identified using a code generated by the Nutratech s.r.l. volunteer’s management software. The code is composed of a letter, five digits, and a letter. Informed consent from participants was required and obtained. Access to the study's raw data is allowed by application only to the study director and the person designated by him to elaborate on the raw data. There are no ethical or legal restrictions to be added. All study procedures were conducted in accordance with the ethical principles of the Declaration of Helsinki.

IPD sharing plan summary

Stored in non-publicly available repository