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The effectiveness of a probiotic food supplement to restore the vaginal microbiota in postmenopausal women

Submission date
03/10/2022

Recruitment status
No longer recruiting

Registration date
06/10/2022

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The existence of communication between the vagina and the gut has long been recognized. It is therefore important to maintain a healthy microbiota community (microorganisms including bacteria that live in the digestive tract) for the regulation of infection in the urogenital tract. Probiotic supplementation has been suggested to maintain, through the gut microbiota, the physiological vagina microbiota with a reduction of pathogen (harmful bacteria) colonization. In this context, the use of probiotics could support women during the postmenopausal period when they are more susceptible to infections. The main aim of this study is to evaluate the effectiveness of a food supplement based on the SynBalance® Femme probiotic formulation at improving the vaginal microbiota and reducing inflammation due to vaginal infections.

Who can participate?
Healthy postmenopausal women, aged 45-65 years

What does the study involve?
The study involves taking food supplements for 28 days. The probiotic product should be taken for 4 consecutive weeks, one capsule per day. Assessments will be carried out at the time of recruitment and the start of the study and at the end of treatment with the food supplement, after 4 weeks. A telephone assessment will be performed after a 4-week follow-up period.

What are the possible benefits and risks of participating?
Risks associated with the intake of the product are considered from low to very low. The benefits associated with product use are improvement of symptoms of postmenopausal and vaginal infections.

Where is the study run from?
Colledoro Medical Centre - Siena (Italy)

When is the study starting and how long is it expected to run for?
April 2022 to March 2023

Who is funding the study?
SynBalance srl (Italy)

Who is the main contact?
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Contact information

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Scientific

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Study information

Scientific Title
Observational prospective study on the efficacy of a food supplement containing a probiotic blend to restore the physiological vaginal microbiota in postmenopausal women

Acronym
Menopause 2022

Study objectives

The main objective of this prospective, observational study is to evaluate the potential effectiveness of a food supplement based on the SynBalance® Femme probiotic formulation in improving vaginal dysbiosis, typical of menopause, and in reducing inflammation due to vaginal infections, mainly caused by aerobic microorganisms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2022, Derming Ethics Committee (Via Valassina 29, 20159 Milano, Italy; +39 (0) 3420399117; adele.sparavigna@derming.com), ref: not applicable

Study design
Prospective single-center interventional non-randomized study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vaginal dysbiosis and vaginal infections

Interventions
50 postmenopausal women, aged between 45 and 65 years will be subjected to oral administration of a food supplement containing the SynBalance® Femme blend, consisting of Lactiplantibacillus plantarum PBS067, Bifidobacterium animalis subsp. lactis BL050 and Lacticaseibacillus rhamnosus LRH020. The probiotic product should be taken for 4 consecutive weeks, one capsule per day.

The assessments relating to the state of health and effectiveness of the treatment will be carried out at the time of recruitment and the start of the study (T0) and at the end of treatment with the food supplement, after 4 weeks (T1). A telephone assessment will be performed after a 4-week follow-up period (T2).

Intervention Type
Supplement

Primary outcome(s)
Composition of the vaginal microbiota. The effect of the probiotic treatment on the initial menopausal vaginal dysbiosis will be evaluated as an increase in lactobacillary presence and an improvement of healthy microbiota. Measured at baseline and 4 weeks.

Key secondary outcome(s))
1. Vaginal pH measured using litmus paper at baseline and 4 weeks
2. Dosage of pro-inflammatory cytokines (IL-6, IL-1β, TNF-α and IL-8) measured using human cytokine ELISA kits at baseline and 4 weeks
3. Vaginal well-being measured using the vaginal health index (VHI) at baseline, 4 and 8 weeks

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Postmenopausal women, aged 45-65 years, with last menstrual cycle more than 18 months ago
2. Women with body mass index (BMI) ≤27 kg/m²
3. Women with vaginal pH ≥5
4. Postmenopausal women with typical menopausal disorders
5. Women who intend to use the probiotic product and undergo checkups

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
65 years

Sex
Female

Total final enrolment
50

Key exclusion criteria
1. Women under hormone therapy (HT)
2. Women with BMI >27 kg/m²
3. Women who intend to use probiotic products or that used them in the last 2 weeks
4. Women with a proven allergy to the product
5. Women who have undergone antimicrobial treatment in the last 4 weeks

Date of first enrolment
19/09/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Italy

Study participating centre
Studio Medico Colledoro
Via Colledoro 9
Siena
Italy
53100

Sponsor information

Organisation
SynBalance srl

Funder(s)

Funder type
Industry

Funder Name
SynBalance srl

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/01/2024	26/02/2024	Yes	No