

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/02/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> 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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 Lactocaseibacillus 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 measure

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.

Secondary outcome measures

1. Vaginal pH measured using litmus paper at baseline and 4 weeks
2. Dosage of pro-inflammatory cytokines (IL-6, IL-1 β , 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

Overall study start date

22/04/2022

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

Age group

Adult

Lower age limit

45 Years

Upper age limit

65 Years

Sex

Female

Target number of participants

50

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

Sponsor details

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Sponsor type

Industry

Website

<https://synbalance-probiotics.com/>

Funder(s)

Funder type

Industry

Funder Name

SynBalance srl

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2023

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