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The beneficial effect on candidiasis of a food supplement based on a formulation of probiotics

Submission date
12/01/2026

Recruitment status
No longer recruiting

Registration date
22/01/2026

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Infections and Infestations

[X] 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
A probiotic dietary supplement containing L. plantarum PBS067, L. rhamnosus LRH020, and B. animalis subsp. lactis BL050 may have a positive impact on the vaginal microbiota. The aim of this study is to demonstrate that this dietary supplement reduces the incidence of vulvovaginal Candida spp. infections and manages the symptoms of candidiasis in women of reproductive age.

Who can participate?
Women aged between 18 and 45 years with a vulvovaginal Candida spp. infection and a history of recurrent vulvovaginal candidiasis, defined as three or more Candida spp. infections in less than 1 year

What does the study involve?
Participants will be randomly allocated to consume one capsule daily of either the supplement or a placebo (dummy). After an initial 2-week treatment period and a subsequent 2-week washout phase, participants will enter a 4-month 'maintenance phase' during which they will take the supplement or placebo for only 1 week per month. Throughout the entire treatment period, participants must visit the study center if they experience one or more symptoms of candidiasis. During the medical visit, a medical evaluation will be conducted to determine the need for antifungal treatment.

What are the possible benefits and risks of participating?
An improvement in the incidence of recurrent symptomatic vulvovaginal infections due to Candida spp., and therefore a reduction in the need for antifungal treatment, is expected following the administration of the supplement. However, it is possible that no benefit will be observed.

Where is the study run from?
COMEGEN Soc. Coop. Sociale (Italy)

When is the study starting and how long is it expected to run for?
January 2026 to July 2026

Who is funding the study?
SynBalance SRL (Italy)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Not applicable

Integrated Research Application System (IRAS)
Not applicable

Protocol serial number
FSYNRVVC24_01

Study information

Scientific Title
Efficacy study of a food supplement based on a formulation of probiotics on the incidence of recurrent symptomatic vulvo-vaginal infections from Candida spp. and on the management of candidiasis symptoms, in women of childbearing age to recurrent vulvovaginal candidiasis: single-centre, randomized, placebo-controlled, double-blind clinical study

Acronym
FSYNRVVC24

Study objectives
The intake of a dietary supplement containing Lactobacillus plantarum PBS067, Lactobacillus rhamnosus LRH020 and Bifidobacterium animalis subs. lactis BL050 has been hypothesized to have a positive impact on the vaginal microbiota. Therefore, the aim of this efficacy study is to demonstrate that the dietary supplement under study is effective in reducing the incidence of symptomatic recurrent vulvovaginal Candida spp. infections and in managing the symptoms of candidiasis in women of reproductive age with recurrent vulvovaginal candidiasis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/12/2024, Ethics committee of CAMPANIA 1 (Via Mariano Semmola 53, Napoli, 80131, Italy; +39 (0)8117770131; comitatoetico@istitutotumori.na.it), ref: 6/24

Study design
Monocentric randomized placebo-controlled double-blind trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vulvovaginal candidiasis

Interventions
Participants will consume one capsule daily of either a probiotic formulation (L. plantarum DSM24937, L. rhamnosus DSM 25568, and B. animalis subsp. lactis DSM25566) or a placebo, according to their randomization group. To mantain the double-blind design, both treatments (food supplements and placebo) will be made unrecognizable as the packaging will be identical, and the dosage forms will be the same in color, shape, weight and taste. After an initial 2-week treatment period and a subsequent 2-week washout phase, participants will enter a 4-month 'maintenance phase' during which they will take the supplement or placebo for only 1 week per month.

Throughout the entire treatment period, participants must visit the study center if they experience one or more symptoms of candidiasis. During the medical visit, a medical evaluation will be conducted to determine the need for antifungal treatment (vulvovaginal swab to confirm Candida spp. infection), and the Sobel scale and the SF-12 questionnaire will be administered.

The study will evaluate the difference between the percentages observed in the two study groups of participants: "responders" (those who did not require antifungal treatment for symptomatic vulvovaginal Candida spp. infections during the 5-month study period, or who only needed antifungal treatment once for symptomatic vulvovaginal Candida spp. infections during the 5-month study period) and "non-responders" (those who required antifungal treatment more than once for symptomatic vulvovaginal Candida spp. infections during the 5-month study period).

A secondary exploratory analysis will be conducted to estimate the percentage of participants falling into the following categories: "responder" (no Candida spp. infection during the 5-month study period); "partial responder" (one Candida spp. infection during the 5-month study period); "no responder" (two or more Candida spp. infections during the 5-month study period).

Intervention Type
Supplement

Primary outcome(s)
The number of recurrent and symptomatic vulvovaginal Candida spp. infections and the need for antifungal treatment. The Candida spp infection is confirmed through a vulvovaginal swab and the need for the antifungal treatment is determined by medical assessment whenever the participants visit the experimental center if they experience at least one typical symptom of candidiasis.

Key secondary outcome(s))
1. Symptoms of recurrent candidiasis measured using the Sobel scale at baseline (T0), at the end of the maintenance period (T5), and at each recurrence onset
2. Pro-inflammatory cytokine profile (IL-17, IL-6, TNF-α) evaluated using swab at baseline (t0) and at the end of the maintenance period (t5)
3. Vulvovaginal microbiome evaluated using swab and eNAT at baseline (t0) and at the end of the maintenance period (t5)
4. Quality of life measured using the Short Form-12 (SF-12) questionnaire at baseline (T0), at the end of the maintenance period (T5), 28 days after the end of the treatment (follow-up – TFW), and at each occurrence of recurrence

Completion date
26/07/2026

Eligibility

Key inclusion criteria
1. Female
2. Aged between 18 and 45 years
3. Capable of understanding and signing the informed consent
4. Capable of understanding and complying with the protocol requirements
5. Negative pregnancy test
6. Negative HIV test
7. Who are not taking, and will not take, any type of medication throughout the study period, except for antifungal treatment for Candida spp. infection, when necessary
8. Who have a history of recurrent vulvovaginal candidiasis (RVVC), defined as three or more Candida spp. infections in less than 1 year
9. Who present with a vulvovaginal Candida spp. infection at the screening phase, confirmed by microbiological culture

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Male
2. Age <18 years and > 45 years
3. Pregnant, suspected to be pregnant, or planning to become pregnant during the study period
4. In the lactation phase
5. Not self-sufficient
6. Who are unwilling to cooperate
7. Who have difficulty attending the study site within the scheduled times
8. Who are deemed ineligible by the investigator due to the presence of other conditions considered incompatible with enrollment and requiring pharmacological treatments

9. Diagnosed with acquired immunodeficiency from HIV
10. With known allergies to the ingredients of the experimental products (active or placebo)
11. Who have other vulvovaginal infections unrelated to Candida spp.
12. Who abuse alcohol, drugs, nicotine, caffeine, or theine

To ensure homogeneous distribution of the type of contraceptive method used by the study participants across the two experimental groups, randomization will be conducted in such a way that both groups will have a similar number of women using oral contraceptives.

Date of first enrolment
23/01/2026

Date of final enrolment
26/01/2026

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
SynBalance SRL

Funder(s)

Funder type
Not defined

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