

# Activity and tolerability of *L. plantarum* P 17630, orally administered $5 \times 10^9$ CFU/capsule

<b>Submission date</b> 03/07/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/01/2018	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Vaginal yeast infections are caused by a yeast called Candida, and symptoms include vaginal itching, burning, discharge, and pain with urination. The aim of this study is to find out whether PLANTAGYN, a probiotic food supplement, reduces the risk of the Candida infection coming back (relapse).

### Who can participate?

Women aged over 18 with recurrent vaginal yeast infections (more than three relapses within 1 year)

### What does the study involve?

Participants are randomly allocated to take either PLANTAGYN or placebo (dummy) oral capsules (one in the morning between meals) for 15 consecutive days, followed by 15 days without taking capsules, for 3 months. At the start of the study and after 45 and 90 days of treatment, the physician performs a clinical examination of the patient (itching, pain, burning, redness, swelling, discharge). Participants tell the clinician if a relapse of Candida infection occurs during the study, specifying the first day of appearance and any other events, including side effects.

### What are the possible benefits and risks of participating?

PLANTAGYN may change the vaginal flora (bacteria), helping to keep it healthy and decreasing the occurrence of vaginal infections. No side effects are expected during the study as PLANTAGYN is a food supplement and is not known to cause side effects.

### Where is the study run from?

Metropolitan Hospital (Romania)

### When is the study starting and how long is it expected to run for?

May 2015 to May 2016

### Who is funding the study?

Proge Farm Srl (Italy)

Who is the main contact?  
Mr Nicu Trincu

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Nicu Trincu

**Contact details**  
222nd Plevnei Road, 3rd Floor  
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060016

## Additional identifiers

**EudraCT/CTIS number**  
2017-002827-97

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
PLANT\_2015\_RO

## Study information

**Scientific Title**  
Activity and tolerability of L. plantarum P 17630, orally administered 5 x 10<sup>9</sup> CFU/capsule (PLANTAGYN) : a multicentre, double-blind, placebo-controlled study

**Acronym**  
PLANTAGYN

**Study objectives**  
Evaluation of the activity and tolerability of PLANTAGYN, a food supplement containing the probiotic strain Lactobacillus plantarum P 17630 5x10<sup>9</sup> (CFU/capsule), administrated orally which goes through the gastrointestinal tract, reaching and colonizing the vaginal epithelium and reducing the risk of relapses of Candida spp. The decrease of relapses will be evaluated as time intervals between relapses increases.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Multicentre double-blind placebo-controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Vaginal candidosis

**Interventions**

The participants were assigned to a treatment sequence using a randomization list which is unknown to the Clinical Investigators and laboratory researchers. Half of the females were treated with PLANTAGYN and half with placebo.

1 capsule/day of PLANTAGYN/placebo, in the morning far from meals, for 15 consecutive days and 15 days of wash out. This administration was repeated for 3 consecutive months.

**Intervention Type**

Supplement

**Primary outcome measure**

Lactobacillary grade (LBG) assessment of vaginal lactobacilli flora, assessed by microscopic vaginal swab examination at t0 (initial visit - baseline), t45 (after 45 days of treatment), t90 (after 90 days of treatment)

**Secondary outcome measures**

1. Genetic identification of the probiotic strain *L. plantarum* P17630 using PCR and the vaginal swabs collected during visits at t0 (initial visit - baseline), t45 (after 45 days of treatment), t90 (after 90 days of treatment)
2. Relapses of *Candida* spp; each patient communicated to the clinician if any relapses occurred during the 90-day follow-up

**Overall study start date**

20/05/2015

**Completion date**

16/05/2016

## Eligibility

**Key inclusion criteria**

1. Women with clinical history of recurrent yeast vaginitis (> 3 relapses within 1 year)
2. Age > 18 years
3. No foods with added probiotics (e.g. yogurts and derivate) and food supplements with probiotics taken in the previous 30 days
4. Ability to follow personal hygiene care
5. The will to cooperate during the study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

150

**Key exclusion criteria**

1. Women with clinical symptoms of yeast or bacterial vaginitis (e.g. burning, itching, odor fish, vaginal discharge, leucorrhea)
2. Ongoing antimicrobial drugs treatment for vaginal infections
3. Laboratory confirmed bacterial infections (exclusion in case of t0 Nugent score > 7)
4. Menopause
5. Pregnancy (drop-out in case of pregnancy during the study)
6. Chronic antibiotic treatment
7. Chronic corticosteroid treatment
8. Immunodeficiency
9. Diabetes
10. Vaginal probiotics used in the previous 30 days
11. Participation to any clinical studies which could influence genitourinary tract flora

**Date of first enrolment**

30/09/2015

**Date of final enrolment**

16/05/2016

## Locations

**Countries of recruitment**

Romania

**Study participating centre****Metropolitan Hospital**

Serban Voda Ave, no. 95-101, district 4

Bucharest

Romania

040204

**Study participating centre****Clinica Obstetrica-Ginecologie II "Dominic Stanca"**

57th, Boulevard 21 Decembrie 1989

Cluj-Napoca

Romania

400124

**Study participating centre****Clinical Hospital of Obstetrics and Gynecology "Cuza Vodă"**

34th Cuza Vodă Street

Iași

Romania

700038

**Sponsor information****Organisation**

Proge Farm Srl

**Sponsor details**

Largo Donegani 4/A

Novara

Italy

28100

**Sponsor type**

Industry

**Website**

[www.progefarm.it](http://www.progefarm.it)

ROR

## Funder(s)

### Funder type

Industry

### Funder Name

Proge Farm Srl

## Results and Publications

### Publication and dissemination plan

The dissemination of study results are planned to be published in a high-impact peer reviewed journal at the end of July 2017.

### Intention to publish date

31/07/2017

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study (source documentation, CRFs) will be stored in a repository (CEBIS warehouse). Consent was obtained from participants.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2018		Yes	No