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Activity and tolerability of L. plantarum P 17630, orally administered 5 x 10 9 CFU/capsule

Submission date 03/07/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/07/2017	**Overall study status** Completed	
Last Edited 31/01/2018	**Condition category** Infections and Infestations	

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
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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 9 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 5x109 (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)

The Ethics Committee of the University of Medicine & Pharmacy “Târgu Mureş”, Romania, 20/05 /2015, ref: No.66

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

ROR

https://ror.org/023k9vr64

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?
Results article	results	01/01/2018		Yes	No