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A sustained-release pessary containing oligomeric lactic acid for the treatment of bacterial vaginosis

Submission date
21/02/2014

Recruitment status
No longer recruiting

Registration date
21/03/2014

Overall study status
Completed

Last Edited
21/03/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bacterial vaginosis (BV) is one of the most common vaginal infections and affects about 20% of women of fertile age. The most common symptom is smelly vaginal discharge, resulting in decreased quality of life for many women. BV is often recognized as vaginal bacterial imbalance where bad bacteria dominates the vaginal microbial population and the good bacteria have been put aside. If not treated, BV can result in a wide range of medical complications. In this study we are testing a new treatment, a vaginal pessary. This is based on modified lactic acid [(oligomeric lactic acid (OMLA)] where lactic acid is gradually released into the vagina over several days to restore the natural vaginal acidity. The aim of the gradual release of lactic acid is to make it easier for women as they do not need to dose more frequently than once or twice a week, as compared to every day as for most products on the market. Apart from treating the BV, the new OMLA pessary treatment was designed to be safe and user friendly.

Who can participate?
Adult women with confirmed BV, as assessed by a doctor at one of the participating clinics, can take part in the study.

What does the study involve?
The study consisted of two parts, one part with 21 patients followed by a larger confirmatory part (105) where the new treatment was compared to controls. In the first part of the study, patients were treated for two weeks and visited the clinic five times (day 1, 4, 8, 11 and 15). Patients received the new treatment once a week or twice a week. In the second part of the study, (on different patients) patients were treated for one week only. The patients attended at least three clinic visits (day 1, 4 and 8). Participants were randomly allocated to one of the following three groups: treatment with the pessary once a week for 1 week, treatment with the pessary twice a week for 1 week, or the control group, who did not receive any treatment for the first week so that the natural progress of BV could be studied. Control patients with confirmed BV at completion of study week 1 were then randomly allocated to receive treatment with the pessary either once or twice a week for 1 week. At each clinic visit a gynaecologic examination was performed by the investigator/doctor to assess BV, including pH measurement. Any side

effects were recorded and the patients had to complete a questionnaire related to the treatment.

What were the possible benefits and risks of participating?
By joining the study the patients could receive a treatment resulting in clearance of BV. No alarming side effects are expected as the treatment is based on well-known ingredients. Patients can withdraw from the study should they wish.

Where is the study run from?
The study was performed at nine primary care clinics and one clinical research unit for women located at Karolinska University Hospital, Sweden.

When is the study starting and how long is it expected to run for?
The study started in March 2011 and ran until June 2012.

Who is funding the study?
Laccure AB, Sweden.

Who is the main contact?
Dr Margareta Fredstorp
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LAC-CIP-10-001

Study information

Scientific Title
Efficacy, safety and user-friendliness of a novel sustained-release oligomeric lactic acid pessary in the treatment of patients with confirmed bacterial vaginosis: a randomized multicenter open-label parallel-group two-part study

Study objectives
To evaluate the efficacy, safety and patient acceptance of two dosing frequencies of oligomeric lactic acid (OMLA) sustained-release pessary compared to controls in patients with bacterial vaginosis (BV). The main aim was to show that the proportion of treatment successes was different in the OMLA pessary group (once a week) compared with the untreated control group. Treatment success was defined as no BV at day 8 (V3) according to Amsel's criteria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Central Ethical Review Board (Sweden), 04/03/2011, ref: Ö 2-2011
2. Swedish Medical Products Agency (MPA), 13/12/2010, assigned document No./diarie nr 461: 2010/525431
There were in total three amendments that were also approved by the Ethics Committee and the MPA.

Study design
Randomized controlled parallel-group multicentre open-label two-part study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Bacterial vaginosis

Interventions
The study consisted of two parts: a proof-of-concept part A followed by a larger confirmatory part B. The OMLA pessary was self-administered at bedtime according to given (written) specific advice.

In part A the participants were randomized to one of the following two groups:
1.Treatment with the OMLA pessary once a week for 2 weeks (OW)
2.Treatment with the OMLA pessary twice a week for 2 weeks (TW)

In part B the participants were randomized to one of the following three groups:
1.Treatment with the OMLA pessary once a week for 1 week (OW)
2.Treatment with the OMLA pessary twice a week for 1 week (TW)
3.The control group (CG) did not receive any treatment intervention for the first week. Control patients with confirmed BV at completion of study week 1 were randomized to receive study treatment with the OMLA pessary either once or twice a week for 1 week.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oligomeric lactic acid (OMLA)

Primary outcome measure
Frequency of patients with no bacterial vaginosis (BV) according to Amsel's criteria after 1 week in the once a week OMLA pessary treatment group compared with the control group.

Secondary outcome measures
1. Frequency of patients with no BV after 1 week in the group treated twice a week with OMLA pessary (TW) vs the control group (CG), as well as in the once a week (OW) vs the twice a week group (TW) and the pooled OMLA pessary treatment groups (OW+TW) vs the control group
2. Frequency of patients after 1 week (day 8) positive for each of the four Amsel criteria in each treatment arm
3. Change in vaginal pH over time (day 4 and day 8) compared to baseline in each study arm
4. Patient treatment satisfaction after completed treatment in each treatment arm
5. Frequency of spontaneously reported adverse events during treatment in each treatment arm
6. Proportion of patients with any adverse findings upon vulvo-vaginal mucosa examination on day 8 compared to baseline

Overall study start date
01/03/2011

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Females at least 18 years of age
2. Confirmed current diagnosis of bacterial vaginosis (determined at study screening) using Amsel's criteria
3. Subjects who are willing to refrain from the use of all other vaginal products throughout the study except for intrauterine device

4. Subjects must abstain from sexual intercourse or use condoms throughout the duration of the study
5. Women of child-bearing potential must have a negative urine pregnancy test result upon entry into the study
6. Subject is willing to answer questions mainly related to product acceptability but some that are related to sexual activity
7. Subjects who are able to give written informed consent and agree to follow-up on time

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
128 patients

Key exclusion criteria
1. Women planning to become pregnant during the study period
2. Menstruating at the time of the diagnosis or anticipate the onset of menses during the course of the study
3. Post-menopausal women (definition: a woman experiencing 12 consecutive months of amenorrhea)
4. Received vaginal or oral antibiotics or pH restoring product(s) within two weeks prior to study enrolment
5. Subjects with yeast or trichomonas infection, diagnosed by microscopy
6. Suspicion of low genital tract infection, e.g. chlamydia or gonococcus infection
7. Subject with signs of vulvovaginal irriation where concomitant vaginal disease is suspected
8. Subjects who have participated in another clinical trial or have taken an experimental drug within the past 30 days
9. Subjects previously participated in this study

Date of first enrolment
01/03/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Sophiakliniken
Lund
Sweden
22223

Sponsor information

Organisation
Laccure AB (Sweden)

Sponsor details
Kullagatan 8
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Sweden
21774

Sponsor type
Industry

Website
http://www.laccure.com/

ROR
https://ror.org/05nmp7m26

Funder(s)

Funder type
Industry

Funder Name
Laccure AB (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration