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Use of vitamin C tablet in the prophylaxis of bacterial vaginosis relapses

Submission date
11/10/2012

Recruitment status
No longer recruiting

Registration date
24/10/2012

Overall study status
Completed

Last Edited
24/10/2012

Condition category
Infections and Infestations

[_] 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 a common condition that affects almost one third of childbearing age women. The cause of BV is still unclear, but currently it is considered to be characterized by depletion of Lactobacillus spp. and an intense increase of vaginal anaerobic bacteria leading to a replacement of Lactobacilli and an increase in vaginal pH. The study aimed to evaluate the potential effect of vitamin C in preventing BV relapses in patients previously cured after a BV episode.

Who can participate?
Out-patient women, aged between 18 and 50 years, with recurrent bacterial vaginosis (BV).

What does the study involve?
Participants were randomly allocated to receive either vitamin C or placebo. Women were instructed to insert the tablets deeply into the vagina at bedtime and were supplied with 250mg vitamin C (ascorbic acid) tablets or a matching placebo (dummy).

What are the possible benefits and risks of participating?
Benefits of participating in the study was maintaining a normal vaginal acidity. No particular risks were foreseen if taking part in the study, however participants my feel some discomfort at the application site like burning and/or itching.

Where is the study run from?
From nine European sites, in Italy (Pavia, Palermo, Lavagna Genova), Germany (Freiburg), Russia (Moscow), Ukraine (Donezk), Portugal (Porto) and The Netherlands (Dordrecht).

When is study starting and how long is it expected to run for?
The study was carried out between April 2005 and September 2008.

Who is funding the study?
Polichem SA, Lugano, Switzerland

Who is the main contact?
Dr Paola Magnani
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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
PM0316

Study information

Scientific Title
A randomized, comparative, double-blind, placebo-controlled, parallel group study to evaluate the efficacy of a 250 mg Vitamin C vaginal tablet - as prophylaxis of recurrent bacterial vaginosis

Study objectives
To evaluate the effect of vitamin C 250 mg vaginal tablets in comparison to placebo on bacterial vaginosis relapses occuring during the 6-cycle period of prophylaxis in women with a previous episode of bacterial vaginosisv (BV) cured with either metronidazole or clindamycin accoridng to the local therapeutic protocols.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitato di Bioetica Azienda di Rilievo Nazionale e di Alta Specializzazione Ospedale Civico e Benfratelli - Palermo - Italy

Comitato Etico Regione Liguria Azienda sanitaria locale N.4 Chiavarese Chiavari (GE) Italy
Comitato di Bioetica - I.R.C.C.S. Policlinico S. Matteo - Pavia Italy
Lokale Toetsingcommissie - Albert Schweitzer Ziekenhuis, lok. Amstelwijk Dordrecht The Netherlands
Ministry of Health of Ukraine -Donetsk State Medical University M. Gorky - Donetsk - Ukraine
Ethics committee at Federal Drug Quality Control - Moscow -Russia
Ethik Kommission der Albert-Ludwigs Universität Freiburg - Germany
Comissão de Etica da Maternidade de Julio Dinis - Porto - Portugal

Study design
Multicenter randomized double-blind placebo controlled parallel group 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Prophylaxis of bacterial vaginosis

Interventions
Women, cured (confirmed by the absence of 3 out of 4 Amsel criteria) from an episode of BV by an antibiotic treatment course of either metronidazole or clindamycin, were randomly assigned to receive vitamin C 250 mg vaginal tablets or placebo as prophylaxis for 6 monthly cycles, starting within 24 hours from the determination of BV cure. The patients applied 1 vaginal tablet once a day for 6 consecutive days per month after menses.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to the first BV relapse (according to Amsel criteria) in the 2 groups during the period of prophylaxis.

Secondary outcome measures
1. Vaginal signs and symptoms (Erythema, Oedema, Fissures, Odour, Itching, Burning, Dysuria, Discharge) assessed by means of a four-point scale: 1=absent; 2=mild; 3=moderate; 4=severe

2. Measurement of vaginal pH
3. Investigators and subjects judgement on product acceptability and tolerability assessed by means of a four-point scale: 1= very good, 2= good, 3=fair, 4= poor, 5= very poor
4. Assessment of adverse event (AEs) occurring at any time during the study

Overall study start date
02/04/2005

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Age ≥ 18 years and < 50 years
2. Medical history positive for recurrent BV episodes (≥ 2 by years)
3. Regular menses
4. Diagnosis of BV (≥ 3 out of 4 Amsel criteria) at enrolment
5. Cure from the current BV episode (≤ 3 out of 4 Amsel criteria) with either metronidazole or clindamycin, according to the local therapeutic protocols
6. Written informed consent
7. Co-operative and reliable women

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
142

Key exclusion criteria
1. Subjects with known hypersensitivity to ascorbic acid or to any of the ingredients
2. Metrorrhagia, polymenorrhea, amenorrea
3. Current or previous infections due to Neisseria gonorrheae, Treponema palidum, Herpes genitalis during the last 2 weeks before enrolment
4. Current or previous infections due to Candida spp. or to Trichomonas vaginalis during the last 2 weeks before enrolment
5. Concomitant treatment with local antibiotics, such as metronidazole and clindamycin, during the study prophylaxis
6. Concomitant use of local acidifying agents, disinfectants, Lactobacillus preparations or vaginal douching during the last 2 weeks before enrolment and during the study period
7. Immunodepression, including HIV positive patients

8. Concomitant neoplastic diseases under treatment
9. Ongoing pregnancy of women willing to be pregnant during the study period
10. Participation to clinical trials with investigational drug / devices during the last 3 months before enrolment
11. History of alcohol and drug abuse
12. Subjects likely to be not compliant or uncooperative

Date of first enrolment
02/04/2005

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Germany

Italy

Netherlands

Portugal

Russian Federation

Ukraine

Study participating centre
Libero
Palermo
Italy
90100

Sponsor information

Organisation
Polichem SA (Switzerland)

Sponsor details
c/o Renata Palmieri
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6912

Sponsor type

Industry

Website
http://www.polichem.com/

ROR
https://ror.org/05735qy63

Funder(s)

Funder type
Industry

Funder Name
Polichem SA (Swizerland)

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