

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

Submission date 11/10/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/10/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/10/2012	Condition category Infections and Infestations	☐ 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 may 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
paola.magnani@polichem.com

Contact information

Type(s)
Scientific

Contact name
Prof Luigi Alio

Contact details
Libero
Obstetrics and Gynaecology
Ospedale Civico e Benfratelli
Palermo
Italy
90100

Additional identifiers

Protocol serial number
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 occurring during the 6-cycle period of prophylaxis in women with a previous episode of bacterial vaginosis (BV) cured with either metronidazole or clindamycin according 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 Ética da Maternidade de Julio Dinis - Porto - Portugal

Primary study design

Interventional

Study design

Multicenter randomized double-blind placebo controlled parallel group study

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Subjects with known hypersensitivity to ascorbic acid or to any of the ingredients
2. Metrorrhagia, polymenorrhea, amenorrhea
3. Current or previous infections due to *Neisseria gonorrhoeae*, *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)

ROR

<https://ror.org/05735qy63>

Funder(s)

Funder type

Industry

Funder Name

Polichem SA (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration