

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

<b>Submission date</b> 11/10/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/10/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
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Palermo  
Italy  
90100

## 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 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

### **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  $\geq 18$  years and  $< 50$  years
2. Medical history positive for recurrent BV episodes ( $\geq 2$  by years)
3. Regular menses
4. Diagnosis of BV ( $\geq 3$  out of 4 Amsel criteria) at enrolment
5. Cure from the current BV episode ( $\leq 3$  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, 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)

**Sponsor details**

c/o Renata Palmieri

Lugano

Switzerland

6912

**Sponsor type**

Industry

**Website**

<http://www.polichem.com/>

**ROR**

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

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Polichem SA (Switzerland)

## **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