

# The effect of compound Lactobacillus on the reproductive tract of childbearing-aged women

<b>Submission date</b> 05/05/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/10/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The microorganisms of the reproductive tract are critical to women's reproductive health, and the vaginal microorganisms of healthy women of reproductive age are dominated by the bacteria Lactobacillus. Studies have shown that clinically confirmed or unexplained vaginal infectious diseases are associated with an imbalance in vaginal microbes. The study will evaluate the effect of compound lactic acid bacteria in regulating the symptoms and indicators of reproductive tract health, will evaluate the colonization of vaginal strains after oral administration of three strains, will analyze the change of vaginal microorganisms, and also discuss the potential mechanism of the effect of probiotic strains on the vaginal environment.

### Who can participate?

Women aged 18-55 years with a vaginal pH of over 4.5

### What does the study involve?

Participants will be randomly allocated to the intervention group or the control group. The intervention and control groups receive one sachet of probiotic solid drink or placebo (dummy) orally with meals daily for one menstrual cycle without interruption during menstruation. Participants are required to take stool and vaginal discharge samples before the intervention, on day 7, day 14, and 2-3 days after the end of the next menstrual period, and to complete the research questionnaire before the intervention, on day 7, day 14, day 21, and 3-5 days after the end of the next menstrual period.

### What are the possible benefits and risks of participating?

The intervention may help regulate the vaginal micro-ecosystem and promote reproductive tract health. Participants in the control group may have no direct benefits. The main risk of the study is that symptoms such as bloating and diarrhea will occur briefly at the beginning of the intervention and will disappear after a short time.

### Where is the study run from?

BGI Precision Nutrition (Shenzhen) Technology Co., Limited (China)

When is the study starting and how long is it expected to run for?  
December 2022 to September 2024

Who is funding the study?  
BGI Precision Nutrition (Shenzhen) Technology Co., Limited (China)

Who is the main contact?  
Rui Zhang, zhangrui16@genomics.cn

## Contact information

**Type(s)**  
Principal Investigator

**Contact name**  
Ms Rui Zhang

**Contact details**  
Floor 6  
Building 11  
Beishan industrial zone  
Yantian Street  
Shenzhen  
China  
518000  
+86 (0)13823223717  
zhangrui16@genomics.cn

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
The effect of compound Lactobacillus on the reproductive tract of childbearing-aged women: a prospective, randomized, double-blind controlled study

**Study objectives**  
1. Lactobacillus compound is more effective than placebo in lowering vaginal pH in sub-healthy women ( $p < 0.05$ )

2. Lactobacillus compound is more effective than placebo in increasing the relative abundance of Lactobacillus in the vagina ( $p < 0.05$ )
3. Lactobacillus compound is more effective than placebo in increasing the relative abundance of the three vaginal species ( $P < 0.05$ )
4. Lactobacillus compound is more effective than placebo in increasing the relative abundance of Lactobacillus in the feces ( $P < 0.05$ )
5. Lactobacillus compound increases the relative abundance of the three species in the feces better than placebo ( $P < 0.05$ )
6. Lactobacillus compound is well tolerated and the incidence of product-related adverse events is not higher than placebo ( $P < 0.05$ )

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 13/04/2023, The Institutional Review Board of BGI (Comprehensive Building, Beishan Industrial Zone, Yantian District, Shenzhen, Guangdong, China; +86 (0)75536307890; bgi-irb@genomics.cn), ref: BGI-IRB 23056

### **Study design**

Interventional double-blinded randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Home

### **Study type(s)**

Treatment

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Women with a vaginal pH greater than 4.5

### **Interventions**

Participants will be randomly allocated to the intervention group or the control group. The researcher will generate a random sequence with a random number table. The envelope method is used to carry out concealed allocation: 116 opaque envelopes are taken, the envelopes are marked with the number of the injection group, and the grouping information according to the randomisation form is indicated in the envelopes, and the envelopes are sealed. After the participants are enrolled in the group in sequence, the researchers open the envelopes one by one, determine the grouping of the patients according to the distribution plan in the envelope, and extract the corresponding products.

Participants in the intervention group will receive compound Lactobacillus one sachet/day, while participants in the control group will receive a placebo one sachet/day. Participants take the sachet orally with meals daily for one menstrual cycle without interruption during menstruation. Participants are required to take stool and vaginal discharge samples before the intervention, on day 7, day 14, and 2-3 days after the end of the next menstrual period, and to complete the research questionnaire before the intervention, on day 7, day 14, day 21, and 3-5 days after the end of the next menstrual period.

## **Intervention Type**

Supplement

## **Primary outcome measure**

Vaginal pH values are measured using a self-testing vaginal pH kit at baseline, 7, 14, 21, and 2-3 days after the next menstruation

## **Secondary outcome measures**

1. The relative abundance and increase of the three strains in vaginal discharge will be measured using vaginal discharge collection kits at baseline, 7, and 2-3 days after the next menstruation
2. The abundance and increase of Lactobacillus in vaginal discharge will be measured using vaginal discharge collection kits at baseline, 7, and 2-3 days after the next menstruation
3. The detected rate and abundance of the vaginal particular pathogen will be measured using vaginal discharge collection kits at baseline, 7, and 2-3 days after the next menstruation
4. The increase and relative abundance of the three strains in feces will be measured using fecal collection kits at baseline, 7, and 2-3 days after the next menstruation
5. The relative abundance and increase of Lactobacillus in feces will be measured using fecal collection kits at baseline, 7, and 2-3 days after the next menstruation
6. The comparison of alpha-diversity of the fecal microbiota will be measured using fecal collection kits at baseline, 7, and 2-3 days after the next menstruation
7. The increase of the relative abundance of short-chain fatty acid producing bacteria in gut microbiota will be measured using fecal collection kits at baseline, 7, and 2-3 days after the next menstruation

## **Overall study start date**

01/12/2022

## **Completion date**

30/09/2024

# **Eligibility**

## **Key inclusion criteria**

1. Non-menopausal women aged 18-55 years
2. Self-test vaginal pH value over 4.5 at 2 or 3 days after menstruation
3. Willing to stop consuming probiotic supplements (yoghurt excluded) within 1 week of enrollment and to stop consuming fiber supplements during the intervention
4. Sign the informed consent

## **Participant type(s)**

Healthy volunteer

## **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

Female

**Target number of participants**

116-200

**Total final enrolment**

192

**Key exclusion criteria**

1. Menopause
2. Pregnancy, latency, and prepared pregnancy
3. Systemic antibiotic exposure 1 week before enrollment
4. Diagnosed with the systematic disease
5. History of gastrointestinal surgery or cancer
6. Diagnosed with the reproductive disease
7. Atopic, or allergy to the known ingredient of the product

**Date of first enrolment**

01/06/2023

**Date of final enrolment**

01/08/2024

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**BGI Genomics Co., Ltd. BGI Youkang out-patient department**

1101-1105, Unit 1, Building 1

Shenyan Road

Haishan Street

Yantian District

Shenzhen

China

518000

# Sponsor information

## Organisation

BGI Precision Nutrition (Shenzhen) Technology Co., Limited

## Sponsor details

Floor 6, Building 11  
Beishan industrial zone  
Yantian Street  
Shenzhen  
China  
518000  
+86 (0)13246430421  
zhongyiyi@genomics.cn

## Sponsor type

Industry

# Funder(s)

## Funder type

Industry

## Funder Name

BGI Precision Nutrition (Shenzhen) Technology Co., Limited

# Results and Publications

## Publication and dissemination plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

## Intention to publish date

31/10/2026

## Individual participant data (IPD) sharing plan

The researchers will upload all the biometric information to databases and provide all the clinical phenotype data of participants after the research article is published

## IPD sharing plan summary

Published as a supplement to the results publication