Effects of over-the-counter lactic acid-containing vaginal douching products on the vaginal microbiota

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41739

Source
ToetsingOnline

Brief title
Vaginal hygiene study

Condition

- Other condition
- Bacterial infectious disorders

Synonym
Bacteriële vaginose, disbalance of the vaginal microbiota

Health condition

seksuele gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: R&D fonds van de GGD Amsterdam

Intervention

Keyword: Bacterial vaginosis, Lactic acid-containing douching product, STI susceptibility, Vaginal microbiota

Outcome measures

Primary outcome

For each participant, the vaginal microbiota composition before initiation of product use, during product use, and after cessation of product use will be assessed by next generation sequencing.

For a general overview of the fluctuations in the composition of the vaginal microbiota over time, the sequencing results will be depicted in heatmaps.

Furthermore, independent determinants for fluctuations in the composition of the vaginal microbiota will be determined by logistic regression analysis, linear discriminant analysis effect size, and principal component analysis.

We will also track specific bacterial species that are associated with the normal vaginal microbiota and with BV, such as lactobacillus species, Gardenerella vaginalis, and Atopobium vaginae.

We will use Nugent scoring and Amsel criteria to determine the BV status over time.

Secondary outcome

Not applicable

Study description

Background summary

Women worldwide engage in different vaginal practices, like herbal steambaths, herbal insertions into the vagina, or intra-vaginal douches and they have a wide variety of reasons to do so. With intra-vaginal douching a douching device is placed into the vagina to spray a liquid. This is a common practice among women in Western countries. Moreover, these products are widely available and advertised on TV even though the biologic effects of these products for vaginal use, including the effects on the vaginal microbiota, have barely been studied by independent researchers and are therefore not known.

Bacterial vaginosis (BV) is an imbalance of the microbial vaginal flora characterised by a decrease of lactobacilli and an increase of other anaerobic and/or facultative anaerobic bacteria.

Study objective

The aim of our pilot intervention study is
1) to describe the effects of lactic acid-containing vaginal douching on the vaginal microbiota dynamics using novel molecular laboratory methods.
2) to describe the effect of lactic acid-containing vaginal douching on the change in BV status using validated clinical and microscopic criteria (Nugent and Amsel scores).
The goal of our study is to improve the sexual and reproductive health of women. Results will also contribute to public health recommendations regarding the use of lactic acid-containing vaginal douching products.

Study design

Prospective pilot intervention study.
Women will self-collect vaginal swabs during three menstrual cycles. The first cycle women will refrain from using any vaginal douche product. The second cycle women will use the lactic acid-containing douching product 3 times a week (eg, Monday, Wednesday, Friday) for 4 weeks. The third cycle women will again refrain from using any vaginal douche product.

Intervention

The over-the-counter available Etos® Intiem vaginale douche and Etos® Intiem vloeistof.

Study burden and risks

All participants with vaginal infections will be offered treatment at the study site according to the guidelines used by the STI clinic for the management of sexually transmitted infections.

Participation in this study probably poses no risk. Indirectly, information gained from this study may lead to increased knowledge about changes in vaginal microbial composition after use of lactic acid-containing douching products, and about risk factors for BV.

This study involves identification of microbiologic effects of lactic acid-containing vaginal douching products. Health-related data can be used to monitor the occurrence of vaginal infections in the female population. The products used for the intervention are licensed as over the counter products and the sample collection imposes no additional risk to the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Women of reproductive age between 18-36 years

Exclusion criteria

Pregnancy or pregnancy wish
STI diagnosis
Age <18 and >36 years
Irregular menstruation
Use of antibiotics in the last 30 days
Known gynaecological pathology

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	28-05-2015

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51808.018.14