Evaluation of multiplex PCR for diagnosing bacterial vaginosis and candidiasis in fluor vaginalis

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The aim of this pilot study is validate the multiplex PCR for bacterial vaginosis and candidiasis on the basis of Nugent score, Amsel criteria, clinical diagnosis of candidiasis and culture before and after treatment. Besides that we will measure...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON42189

Source
ToetsingOnline

Brief title
FluVa-study

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
Bacterial vaginosis and candidiasis - vaginal (yeast) infections

Research involving
Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis
Source(s) of monetary or material Support: Bronovo research fonds

Intervention

Keyword: Bacterial vaginosis, Candidiasis, Fluor vaginalis, Multiplex PCR

Outcome measures

Primary outcome

A. Outcome of culture on Gardnerella vaginalis, C. albicans, yeasts,

trichomoniasis and beta-hemolytic streptococcal infections

- Positive

- Negative

- can't be measured

B. Outcome gram-stain for bacterial vaginosis

- Positive

- Negative

- can't be measured

C. Outcome Multiplex PCR analysis on bacterial vaginosis, atopobium vaginae,

lactobacillus spp.

Negative

1. Normocenosis: normal vaginal flora

Positive

Anaerobic disbiosis: bacterial vaginosis with explanation disbalanced vaginal

flora, significantly more anaerobe bacteria

Doubtful positive

3. Mezocenosis: changed vaginal flora with increased anaerobe bacteria.

4. Unexplained disbiosis: decreased lactobacillus, no increase of anaerobe bacteria.

Can't be measured

5. Result of test is unreliable: not specified but will be given to a specific grade of Cq of total bacteria.

D. Outcome Multiplex PCR analysis on Candida species: AmpliSens C. albicans, C. glabrata, C. krusei-MULTIPRIME-FRT PCR.

- Positive
- Negative
- can't be measured

E. Outcome PCR analysis on Trichomoniasis

- Positive
- Negative
- can't be measured

F. Outcome PCR analysis on C. trachomatis

- Positive
- Negative
- can't be measured

G. Outcome PCR analysis on N. gonorrhoeae

- Positive

- Negative

- can't be measured

Secondary outcome

Clinical diagnoses based on complaints and vaginal inspection on which we give

a treatment.

- Bacterial vaginois

- Candidiasis

- Trichomoniasis

- Infection with ß -hemolytic streptococcal group A

- C. trachomatis

- N. gonorrhoeae

Presentation of symptoms

- Duration of symptoms

- Amount of discharge

- Color discharge

- Fishy odor of discharge

- Fishy odor of discharge after intercourse

- Itching

- Burning

- Vaginal redness of irritation

- Pain

- Symptoms related to menstruation cycle

- Dyspareunia

- Seriousness of complaints

- Bleeding after intercourse

- Symptoms gone after treatment

- Dysuria

- Abdominal pain

Physical examination

- Vaginal redness or irritation

- Amount of discharge

- Color of discharge

- Friable white discharge

- Frothy white discharge

- Purulent discharge

- Bleeding cervix at speculum examination

- Erythematous cervix

- Fishy odor of discharge

- Fishy odor after KOH

- Acidity of discharge

- Clue cells on wet mount

- Motile trichomonads on wet mount

- Budding yeast, pseudohyphae, and hyphae on a wet mount of the discharge;

adding 10 percent potassium hydroxide

Time needed to do the following test in minutes

- Acidity measurement

- whiff-amine test

- Microscopial evalution with wet mount or potassium hydroxide

Outcome microbioma analysis with bacterial 16S rDNA analysis by nex-gen

sequencing (Illumina MiSeq)

- Positieve

- Negative

- Can't be measured

Study description

Background summary

Fluor vaginalis is the most common gynecological problem in the general practitioners practice with an incidence of 40 á 50 per 1000 female patients a year. Candidiasis and bacterial vaginosis are the most common causes of discharge problems. Bacterial vaginosis can cause preterm delivery, post postpartum fever, endometritis after curettage and endometritis after a cesarean. The diagnosis candidiasis and bacterial vaginosis both can be made on clinical view in combination with bedside diagnostics (Amsel criteria), and/or culture, and/or cytology. The NHG standard (general practioners standard) advises to do bedside diagnostics (Amsel criteria) but these are labor-intensive with limited sensitivity and specificity. Recently there is a multiplex PCR analysis available for diagnosing bacterial vaginosis and candidiasis. The aim of this pilot study is to evaluate the multiplex PCR for diagnosing bacterial vaginosis and candidiasis in fluor vaginalis patients.

Study objective

The aim of this pilot study is validate the multiplex PCR for bacterial vaginosis and candidiasis on the basis of Nugent score, Amsel criteria, clinical diagnosis of candidiasis and culture before and after treatment.

Besides that we will measure the time needed to do whiff-amine testing and analysing wet mount slides for a possible cost-benefit analysis.

Study design

This study contains pregnant and non-pregnant women who visit the gynecological outpatient clinic in the Bronovo hospital and Roosevelt clinic with discharge complaints. The control group contains women without specific discharge complaints. There will we take medical history, physical evaluation and 3 forms of diagnostic tests (culture, PCR and gram-staining).

The control group is needed for validation of the Multiplex PCR. When the multiplex PCR is proper functioning it is expected that is gives the same negative result as the gold standard for bacterial vaginosis and candidiasis in women without complaints.

Because this is a pilot study and a power analysis can not yet be made there will be included 60 women with discharge complaints and 20 women without discharge complaints. The time of inclusion will take 2 till 3 months.

Patients will be treated on clinical diagnosis or if unclear on PCR analysis outcome. There will be a follow up after 4 weeks where response on therapy will be determined and where vaginal swabs will be taken for the second time. The control group will also have a follow up in 4 weeks at the gynaecologie outpatient clinic or at the Roosevelt clinic. For validating the multuplex PCR we want to have insight into the reproducebility and variation of the vaginal flora of the patient without complaints.

Study burden and risks

The burden for patients will consist of 2 measuring moments, first at presentation of symptoms, taking history, examination of the vagina and taking 3 vaginal swabs. Second at follow up in 4 weeks, evaluation of therapy (if given), vaginal swabs and wet mount will be taken again. There are no risks associated with participation in this study. Benefits for the patient while participating is a comprehensive analysis of discharge complaints and an accurate follow-up.

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

Major criteria:
Increase of discharge
Odor of discharge;Minor criteria:
Color change of discharge
Itching, irritation or redness

Exclusion criteria

Postmenopausal women
Immune compromised women
Women who had a vaginal ultrasound with gel on the day of inclusion
Women with complaints of vulva in stead of vagina
Women who have been treated with antibiotics or clotrimazole for vaginal infections the last 3 months

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-02-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	13-04-2015
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51257.098.14