

Efficacy of Multi-Gyn ActiGel for treatment of vaginal infections

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22559

Source

NTR

Health condition

Vaginal discomforts; bacterial vaginosis; vaginal yeast infection; candidiasis

Sponsors and support

Primary sponsor: Sponsor: BioClin BV, Delft, The Netherlands

Performer:

Dr. Unnop Jaisamrarn

Associate Professor

Dept. of Obstetrics and Gynecology

Faculty of Medicine

Chulalongkorn University

Bangkok, Thailand

Source(s) of monetary or material Support: BioClin BV, Delft, The Netherlands

Intervention

Outcome measures

Primary outcome

- Clinical cure of vaginal infection as diagnosed by the investigator
- Reduction in severity of patient vaginal complaints

Secondary outcome

- Clinical cure of vaginosis as diagnosed by the investigator
- Reduction in severity of vaginitis as observed by the investigator
- Reduction in severity of specific symptoms of vaginal discomforts, i.e. relief of itch, discharge, malodor, burning, pain
- Subgroup analysis for improvement of microscopic evaluations (Nugent score, yeast cells, granulocytes)

Study description

Background summary

Many women suffer from vaginal infections (mostly candidiasis or bacterial vaginosis) and associated complaints such as itch, malodor and abnormal discharge. Although these conditions hardly ever have serious medical consequences, they can severely affect the quality of life of women that suffer from these conditions. Standard treatment of vaginal infections consists of antibiotic or antimycotic therapy, but these drugs have several side-effects and also recurrence rates are very high. Multi-Gyn ActiGel is a natural alternative to antimicrobial agents that contains patented anti-adhesive polysaccharides (called 2QR-complex) to correct the healthy vaginal microflora. In this study we aim to assess the efficacy of ActiGel over a placebo gel to treat vaginal infections and the associated complaints. Multi-Gyn ActiGel is a substance-based medical device class IIa.

Study objective

Multi-Gyn ActiGel is effective to treat vaginal infections and relief symptoms related to this condition.

Study design

Women will be treated for 5 days, and will return to the gynaecologist between day 5-8 from the start of treatment

Intervention

Women that present themselves with a vaginal infection at the gynaecologist will use Multi-

Gyn ActiGel or placebo for 5 days, twice per day. At study entry and at follow up women will be physically examined, and a vaginal swab will be obtained for microscopy, cytology and pH measurement.

Contacts

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Eligibility criteria

Inclusion criteria

- Women suffering from a vaginal infection
- Age between 18 and 60 years

Exclusion criteria

- Women with a sexually transmitted disease
- Pregnancy or planned pregnancy during the study period

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2015
Enrollment:	140
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	18-09-2015
Application type:	First submission

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
NTR-new	NL5331
NTR-old	NTR5440
Other	221/56 : IRB Chulalongkorn University

Study results