Efficacy of Multi-Gyn ActiGel for treatment of vaginal infections

Gepubliceerd: 18-09-2015 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22559

Bron
Nationaal Trial Register

Aandoening

Vaginal discomforts; bacterial vaginosis; vaginal yeast infection; candidiasis

Ondersteuning

Primaire 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
Overige ondersteuning: BioClin BV, Delft, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 severele 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Women that present themselves with a vaginal infection at the gyneacologist 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Women suffering from a vaginal infection

• Age between 18 and 60 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Women with a a sexually transmitted disease

• Pregnancy or planned pregnancy during the study period

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-09-2015
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5331
NTR-old	NTR5440
Ander register	221/56 : IRB Chulalongkorn University

Resultaten