

Efficacy of Multi-Gyn LiquiGel for the relief of complaints related to vaginal dryness in post-menopausal women

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Vaginal atrophy in post-menopausal women results in various vaginal complaints, including dryness. Multi-Gyn LiquiGel is a moisturizing gel with osmo-protectant ingredients. We hypothesize that LiquiGel relieves signs and symptoms of vaginal atrophy...

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

Samenvatting

ID

NL-OMON25376

Bron

NTR

Aandoening

vaginal atrophy; vaginal dryness; vaginal complaints

Ondersteuning

Primaire sponsor: BioClin BV, Delft, The Netherlands

Overige ondersteuning: BioClin BV, Delft, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The efficacy of LiquiGel to relieve vaginal dryness as reported by the patient compared to placebo control.

Toelichting onderzoek

Achtergrond van het onderzoek

With the reduction in estrogen levels that occurs during menopause, physiologic and structural changes occur within the vulvovaginal mucosa that lead to a condition commonly called atrophic vaginitis. In this condition, the cells of the vaginal wall are less developed than in the fertile age, and is often associated with reduced production of vaginal secretions.

Although mild genital changes occur in most women, 10-47% of postmenopausal women will develop one or more debilitating symptoms that include vulvovaginal dryness, dyspareunia, itching, irritation/burning and intercourse bleeding.

Vaginal moisturizers can provide relief by supplementing the vaginal fluid to help maintain natural secretions, correct the vaginal pH and improves comfort during intercourse. The aim of the current study is to investigate the efficacy of Multi-Gyn LiquiGel to relief vaginal complaints related to post-menopausal atrophy.

Doel van het onderzoek

Vaginal atrophy in post-menopausal women results in various vaginal complaints, including dryness. Multi-Gyn LiquiGel is a moisturizing gel with osmo-protectant ingredients. We hypothesize that LiquiGel relieves signs and symptoms of vaginal atrophy and improves atrophy scores of vaginal epithelial cells.

Onderzoeksopzet

Women will undergo a physical vaginal examination and smears for cytological analysis will be taken after 0, 1, 4 and 12 weeks.

Onderzoeksproduct en/of interventie

During the first week of treatment, 2 ml of the assigned study product will be applied intravaginally 2 times per day. In the next 11 weeks, 2 ml of the assigned study product will be applied 3 times/week.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

≥ 1 year past their last menstruation

Experiencing at least one of the following complaints of vaginal dryness: vaginal dryness irritation/burning, itch or dyspareunia due to vaginal atrophy related to post-menopause that is moderate or severe in intensity (moderate to severe is defined as a grade of ≥ 4 on a scale of 0-10).

Microscopic atrophy eligibility criterion: < 5% superficial cells.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Any local or systemic current hormone-replacement therapy are used or used in the past 6 months

Any local medication or treatment is used for relief of the complaints related to vaginal dryness.

Use of any medication to treat bacterial vaginosis or vaginal candidiasis in the past 30 days.

Current or recent episode of urogenital cancer

Diabetes

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	80
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: 20-01-2016

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	NL5546
NTR-old	NTR5667
Ander register	METC Sarajevo Bosnia-Herzegovina : MGL BH 001

Resultaten