

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25376

### Source

Nationaal Trial Register

### Health condition

vaginal atrophy; vaginal dryness; vaginal complaints

## Sponsors and support

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

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

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

The efficacy of LiquiGel to reduce discomforts related to post-menopausal atrophy other than

'vaginal dryness' as reported by the patient

The efficacy of LiquiGel to reduce signs of vaginal atrophy as reported by the physician

The efficacy of LiquiGel to improve cytological outcomes related to vaginal atrophy

Improvement of signs and symptoms over time

General patient satisfaction of LiquiGel as compared to placebo

## Study description

### Background summary

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.

### Study objective

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.

### Study design

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

## **Intervention**

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.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

≥ 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.

## Exclusion criteria

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

## 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):	01-03-2016
Enrollment:	80
Type:	Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	20-01-2016
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	NL5546
NTR-old	NTR5667
Other	METC Sarajevo Bosnia-Herzegovina : MGL BH 001

## Study results