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BACKGROUND

Clinical Study Results

A Randomized, Prospective, Double-Blinded, Multicenter Study Comparison of WaterWorks[®], a New Vaginal Cleansing System Versus a Commercially Available Over-the-Counter Douche for Reduction or Abatement of Perceived Vaginal Odor With or Without Complaints of Discharge in Women with No Infectious Cause of Vaginitis

Key results:

- The use of the medical-grade, stainless steel nozzle WaterWorks did not create adverse affects to the vaginal ecosystem.
- Women that used WaterWorks in the clinical studies found it to be successful in reducing or eliminating vaginal odor.

The study's primary endpoint was the reduction or elimination of the subject's vaginal odor safely and effectively as determined after 1 month (4 weeks) of cleansing daily. Subjects used a visual analog scale from "no odor" to "strong offensive odor."

The secondary endpoint was the number of clinically significant adverse affects on the vaginal ecosystem determined by the number of adverse events, the Lactobacillus score, (the "good" bacteria) in a healthy vaginal ecosystem and the Nugent score, which is used to diagnose bacterial vaginosis.

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Pilot Study Results

Vaginal Cleansing With WaterWorks Device for Perceived Vaginal Odor with or Without Complaints of Discharge in Women with No Infectious Cause of Vaginitis: A Pilot Study

Published in Infectious Diseases in Obstetrics and Gynecology, Volume 2006, Article ID 95618, Pages 1-4.

Authors: Doctors Ashwin Chatwani, Sarmina Hassan, Salma Rahimi, Stacey Jeronis and Vani Dandolu at Temple University

The objective of this study was to determine if vaginal cleansing with the WaterWorks cleansing system for one month was safe and effective in reducing or eliminating vaginal odor and not having any adverse affects on the vaginal ecosystem.

Ten women with vaginal odor with no infectious cause of vaginitis with or without discharge used WaterWorks every day for four weeks in an open-label, nonrandomized pilot study. Primary outcome measures included perceived vaginal odor by subject, Lactobacilli score from Nugent score and acceptance of WaterWorks. Secondary outcome included the safety of using WaterWorks.

Key results:

- After one month (four weeks) of using WaterWorks daily, there was significant improvement in vaginal odor and there was no significant change in Lactobacilli score (good bacteria).
- At the end of the four-week study, there was significant improvement. Ninety percent of the women claimed reduction or elimination of perceived vaginal odor and there was no significant change in Lactobacillus (good bacteria). Douching with WaterWorks every day did not wash out good bacteria.

Key conclusion:

- Douching with WaterWorks significantly reduces or eliminates vaginal odor without adversely affecting the vaginal ecosystem.

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