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## **"A Comparison Study of the WaterWorks® Douching Device vs. Commercial OTC Douching Device for the Reduction or Abatement of Perceived Vaginal Odor With or Without Complaints of Discharge in Women With no Infectious Causes of Vaginitis"**

### **Abstract**

#### **OBJECTIVE**

To demonstrate the effectiveness of the medical grade stainless steel Water Works ® Douching Device for treating abnormal vaginal odor without adversely affecting the vaginal eco-system. A randomized controlled trial in comparison with a commercially available over the counter plastic douching device.

#### **METHODS**

In a multicenter study, 140 women were randomized to either Water Works ® or control group in 1:1 ratio. Women with perceived vaginal odor with no vaginal infection douched daily for 4 weeks. A Visual Analog Scale (VAS) consisting of a 10-cm line was used to assess the intensity of vaginal odor during the study visits. Primary outcome included assessment of odor improvement by subject and Nugent score from Gram stain of vaginal secretion. Secondary outcome compared the efficacy and safety of Water Works ® with over the counter control douching device. Each patient underwent a baseline, week 2 and week 4 visits.





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## RESULTS

Success Score was 78% for Water Works<sup>®</sup> and 38.5% for control group. Mean VAS was significantly reduced and Nugent score was maintained in both the groups. In the Water Works<sup>®</sup> group VAS was reduced from  $7.3 \pm 0.3$  to  $1.8 \pm 0.6$  (\*\* $p < 0.001$ ) after 4 weeks. In the control group baseline versus 4 weeks VAS was  $7.2 \pm 0.3$  and  $3.4 \pm 0.8$  (\*\* $p < 0.003$ ).

## CONCLUSION

Women reported significant reduction of vaginal odor after douching with water for 4 weeks without any alteration of vaginal flora. Water Works<sup>®</sup> Douching Device was superior to over-the-counter device, in reducing vaginal odor.

**CLINICAL TRIAL REGISTRATION;** [www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT00417365

