

SUMMARY AND CONCLUSIONS OF ABBOTT RESEARCH GROUP RANDOMIZED CLINICAL STUDY

Abbott Research Group, Inc. performed a randomized, blinded multicenter study comparing the WaterWorks[®] Douching Device and a commercially available over-the-counter douching device to support an expanded claim of the reduction or abatement of vaginal odor of perceived vaginal odor with or without complaints of discharge in women with no infectious cause of vaginitis. Due to Agency feedback after enrollment had begun, part of the study was performed in a single blinded (investigator) condition. The effect of blinding on study results was evaluated.

Subjects were evaluated for infectious causes of vaginitis at each study visit. Assessment of vaginal odor at each study visit was performed using a 10 cm visual analog scale (VAS). Subjects self-treated with the WaterWorks[®] or the control device for a total of 4 weeks, with three study visits across that time period. Subjects douched daily with tap water with both devices using the same amount of water. There was no long term follow up.

Effectiveness was defined as a 4 cm or greater reduction in VAS between baseline and Visit 3. Safety was determined by changes in the vaginal eco-system and adverse events. The determination of the primary endpoint is based on 102 evaluable subjects.

Treatment groups were similar for baseline demographic characteristics, baseline GYN examination findings, VAS scores, Nugent scores, and lactobacillus scores.

For determination of primary endpoint, cases lost to follow-up (n=4) and those who withdrew consent (n=2) were included in the intent-to-treat analysis for this endpoint, yielding a total of 102 evaluable subjects. The proportion of subjects in the WaterWorks[®] Group meeting the success criterion was 78 percent versus a success rate of 38.5 percent for the Control Group. Fisher's exact test comparing the overall success proportions (78.0% for the WaterWorks[®] Group versus 38.5% for the Control Group) rejects the null hypothesis of no difference at a significance level less than 0.0001.

Because the study included both single and double blinded subgroups, success rates were compared and showed that higher success rates were observed in the double blinded group and the rate for the WaterWorks[®] Group remained almost twice that of the Control Group.

Adverse effects on the vaginal Eco-System were quantified by changes in the lactobacillus score and the Nugent Score. Results for the WaterWorks[®] Group were similar to that of the Control Group.

Based on the findings described above, Abbott Research Group, Inc. believes that the clinical evidence supports the claim that the WaterWorks[®] Douching Device reduces or abates perceived vaginal odor in women without discharge and no infectious cause of vaginitis.