

PRESS-RELEASE

Vaginal Probiotic product reduce recurrence rate of Bacterial Vaginosis

A newly published double blind, randomised, placebo controlled study¹⁾ shows that EcoVag[®], a patented vaginal probiotic product from the Danish company, Bifodan, significantly reduces the recurrence rate of Bacterial Vaginosis (BV) following antibiotic treatment.

BV is one of the most frequent vaginal infections and if left untreated may have severe gynaecological and obstetric consequences such as pelvic inflammatory disease, miscarriage and pre-term delivery²⁾. Even if BV is successfully cured with commonly used antibiotics, the recurrence rate has been reported as high as 80% after 9 months³⁾.

The study involved 100 women diagnosed with BV. All women were given a standard antibiotic treatment with Clindamycin vaginal cream (Dalacin[®]). On a randomised basis half of the cured women were treated with one EcoVag vaginal capsule and the other half with an identical placebo capsule per day for 10 days during 3 consecutive menstrual cycles to measure the impact on recurrent infection rates.

The study shows that the recurrent BV infection rate is significantly reduced for the women taking EcoVag. At the study completion, after 6 months 65% of the EcoVag treated women were still BV-free compared to 46% of the placebo treated women ($p < 0.05$).

Comparison of the two groups regarding "time from cure to relapse" was also statistically significant ($p < 0.05$).

Furthermore, the study also confirmed that EcoVag is safe to use.

The study was performed in accordance with GCP/ICH in Drammen, Norway by Principal investigator Assistant Professor, MD, PhD, Dr Per-Göran Larsson;

"Too many women suffer from chronic or frequent recurring vaginal infections. The study shows that this particular probiotic product can reduce the risk of recurrent infections, and substantiates the potential of vaginal applied probiotics to positively influence urogenital health" says Dr. Per-Göran Larsson.

Erik Brandsborg, Director of Research & Development at Bifodan: "The results of the study are a very important milestone and corroborates with findings from in-vitro tests and several in-vivo pilot studies performed with the product. Summarizing the results from these trials, EcoVag is safe to use, can prevent women from getting recurrent BV infections and can offer relief to the many women who suffer from BV associated symptoms like itching and burning.

- 1) Larsson P, Stray-Pedersen B, Rytting KR, Larsen S. Human lactobacilli as supplementation of clindamycin to patients with bacterial vaginosis reduce the recurrence rate; a 6 month, double blind, randomised, placebo-controlled study. *BMC Women's Health* 2008, doi:10.1186/1472-6874-8-3
- 2) Larsson PG, Bergstrom M, Forsum U, Jacobsson B, Strand A, Wolner-Hanssen P. Bacterial vaginosis. Transmission, role in genital tract infection and pregnancy outcome: an enigma. *Apmis* 2005;113:233-45.
- 3) Sobel JD, Ferris D, Schwebke J, Nyirjesy P, Wiesenfeld HC, Peipert J, Soper D, Ohmit SE, Hillier SL. Suppressive antibacterial therapy with 0.75% metronidazole vaginal gel to prevent recurrent bacterial Vaginosis. *Am J Obstet Gynecol* 2006;194:1283-9.

