

Microbiome Therapeutic for Treating Bacterial Vaginosis

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Overview

Treating bacterial vaginosis by performing vaginal microbial transplants (VMT).

Background and Unmet Need

Bacterial Vaginosis (BV) is considered the most prevalent form of vaginal infection in women of reproductive age, affecting from one-quarter to one-third of women. Women suffering from BV report diminished quality of life from symptoms that typically include abnormal, often malodorous vaginal discharge. Additionally, BV increases the risk of upper genital tract infection, sexually transmitted infections (STI), such as HIV and Herpes, complications of pregnancy, pre-term birth, and lower success in fertility treatments. Treatment with antibiotics (either systemic or vaginal) remains disappointing; with a 30% relapse rate of symptomatic BV within three months of initial treatment, and up to 50-70% within a year. Moreover, chronic or frequent antibiotic treatment predisposes treated patients to the risk of vaginal candidiasis. Many women therefore suffer from intractable, persistent or recurrent BV with very limited therapeutic options.

The Solution

The group of Prof. Eran Elinav in collaboration with Hadassah hospital in Jerusalem has developed a potential cure for BV by transplanting the vaginal microbiome of healthy women to those afflicted with BV.

Technology Essence

The collaboration between the Elinav group and Hadassah hospital generated a protocol to transplant microbiome from healthy donors into afflicted women (Fig. 1). Donors were screened for a variety of factors including general health and lacking symptoms of BV for at least 5 years. Vaginal microbiomes were then collected and transferred to women diagnosed with BV. In controlled study women who underwent transplantation were tracked for one year to determine the efficacy of a single treatment and to determine whether additional vaginal microbial transplants were needed. Lastly, the vaginal microbiomes of the recipients were 16s rDNA sequenced to determine compositions of bacterial populations.

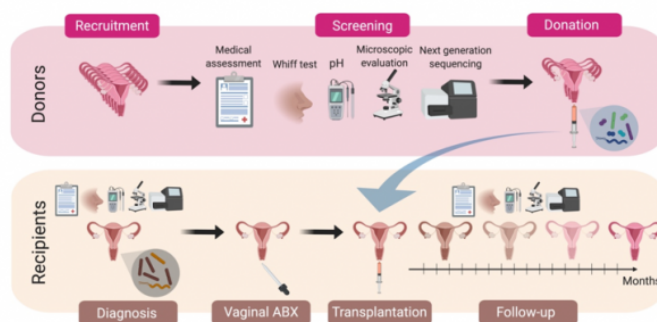


Figure 1: Procedure for vaginal microbiome transplantation whereby determining potential donors involves screening and collection, followed by transplantation and persistent monitoring for months afterwards.

Advantages and Advantages

- A method for treating bacterial vaginosis
- The treatment does not involve antibiotics and does not have the potential for causing or spreading antibiotic resistance
- The method also acts a way to determine who is a viable donor based on the population composition of the vaginal microbiome

Development Status

The current results include clinical results in a cohort of five women with BV, who were tracked for 5-21 months following VMT. Four out of five women showed remission of BV with no symptoms, with the fifth showing incomplete remission. None of the five women showed any adverse effects from the VMT. Current focus is to perform a larger scale clinical trial to determine wider applicability.

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References: Lev-Sagie, A., Goldman-Wohl, D., Cohen, Y. et al. Vaginal microbiome transplantation in women with intractable bacterial vaginosis. Nat Med 25, 1500â€147;1504 (2019).

Clinical Trial Identifier: NCT02236429

Patent Status

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