

Fertility clinics treat abnormal vaginal bacteria aiming to improve reproductive outcome

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In women undergoing in vitro fertilization treatment, pregnancy rates are much lower when women have an imbalance in their vaginal bacteria. Is it possible to correct this problem and increase the pregnancy rate of these women? To find out, five Danish fertility clinics, in collaboration with Statens Serum Institute and Osel Inc., are now conducting a joint clinical research project to improve IVF outcomes by altering the vaginal bacteria.

High levels of two specific vaginal bacteria (*Atopobium vaginae* and *Gardnerella vaginalis*) serve as diagnostic markers of an abnormal vaginal [microbiota](#) that might cause impaired implantation and subsequent poor reproductive outcome.

A recent publication demonstrated that women with an abnormal vaginal microbiota and undergoing IVF had a significantly lower chance of becoming pregnant (9%) compared to women with a normal *Lactobacillus*-dominated vaginal microbiota (44%).

The results of that publication, a collaborative study between the Fertility Clinic, Regional Hospital Skive, Aarhus University, Denmark, Trianglen Fertility Clinic, Denmark and Statens Serum Institute, Denmark, was published in the International Journal, *Human Reproduction*, in 2016.

Approximately 20% of all women in fertility treatment have abnormal vaginal microbiota which can also reside in the upper reproductive tract, i.e. the uterus and the oviducts. Unfortunately, many of these women have no symptoms, so this problem goes unrecognized.

Taken together, these findings convinced the authors to design a study to investigate whether the chance of pregnancy can be improved in these

women by identifying and treating abnormal vaginal microbiota prior to embryo transfer. The study is a joint clinical research project in collaboration with five Danish fertility clinics, Statens Serum Institute and Osel, Inc.

"Ultimately, our success criterion is quite simple, we aim to increase the "baby take-home rate" for women suffering from abnormal vaginal microbiota. Potentially, this study will have great implications for fertility treatment in general. The treatment of abnormal vaginal microbiota might even enable more women to conceive naturally", says MD, PhD student Thor Haahr.

Haahr works at the Fertility Clinic, Regional Hospital Skive and performs the research work in collaboration with Professor Peter Humaidan and Dr. Jørgen Skov Jensen at Statens Serum Institute.

"In a broad sense, researchers are beginning to understand that the bacteria that live on our inner and outer surfaces have a significant impact on our health. We have studied this so-called microbiome and its potential implications for human reproduction, and we found that an intervention based trial is needed to improve our knowledge of cause and effect. Therefore, for this specific trial, we are using a live biotherapeutic drug, LACTIN-V, containing the bacterial species that all studies suggest is the healthiest bacterium in the vagina, *Lactobacillus crispatus*", says Professor Humaidan.

In addition to the Fertility Clinic, Regional Hospital Skive, four additional fertility clinics will cooperate in the trial, including fertility clinics at Copenhagen University Hospital, Holbæk Hospital, and two private fertility clinics Stork VivaNeo and Trianglen, both in Copenhagen. All bacterial analyses will be conducted in collaboration with Dr. Jørgen Skov Jensen at Statens Serum Institute.

The five fertility clinics plan to screen 1,850 [women](#) who undergo first, second or third IVF treatment in order to enroll 333 participants in the trial.

"Of course, only patients who provide their informed consent will participate in the study. Patients who wish to participate during the first screening and are diagnosed with abnormal vaginal microbiota are randomized into three intervention arms. One arm is treated with antibiotics and subsequently with *Lactobacillus crispatus*, a "good" vaginal lactic acid producing bacterium intended to support the restoration of the microbiota in the female reproductive tract and enable more sufficient implantation. Another group is treated with antibiotics only, and the third group is a placebo group", says Haahr. The trial is expected to take up to 2 years to complete.

The research project is also investigating whether or not an abnormal seminal microbiota affects the semen quality and hence the chance of pregnancy. "The bacteria we are investigating are probably also found in the man, but at present there is no evidence to support male treatment", says Haahr.

Provided by Aarhus University

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