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O-264 Vaginal Microbiota Transplantation (VMT) for treatment of vaginal dysbiosis without the use of antibiotics – A Randomized Controlled Trial in healthy women with vaginal dysbiosis

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Study question: Can vaginal microbiota transplantation with shotgun-verified eubiotic vaginal microbiome over three menstrual cycles, convert vaginal dysbiosis to eubiosis in healthy women?

Summary answer: The RCT is ongoing until it is by March 2023. Results will be ready for presentation at ESHRE conference.

What is known already: Vaginal dysbiosis covers imbalances in the vaginal flora, caused by the composition of bacteria, viruses, and vaginal fungi. A large proportion of women who have vaginal dysbiosis do not experience any symptoms. Dysbiosis occurs in about 16-20% of all women. Vaginal dysbiosis is associated with infertility, euploid pregnancy loss, preterm labour or bacterial vaginosis. Treatment of vaginal dysbiosis consists of antibiotic treatment, and/or probiotics. Vaginal transplantation with eubiotic vaginal bacterial flora in combination with antibiotics has successfully been performed in four out of five recipients in an earlier study, but no study has been performed without use of antibiotic pretreatment.

Study design, size, duration: Randomized, controlled, double-blinded trial with a randomization ratio 3:1 to receive either a eubiotic microbiome transplant or placebo. 320 healthy women between 18 and 40 years, was enrolled for screening of vaginal dysbiosis. 30 donors with a eubiotic vaginal

microbiome and 48 recipients with a dysbiotic microbiome were identified. The trial began in June 2021 and will end in March 2023

Participants/materials, setting, methods: Vaginal microbiome composition was assed by next-generation Shotgun sequencing. To qualify as donor bacterial DNA from a vaginal swab had to show a bacterial composition of at least 80% lactobacilli and less than 5% pathogenic bacteria. To qualify as recipient vaginal microbiome composition should be with at least 20% pathogenic bacteria and no more than 10% lactobacilli. The recipient could have up to three attempts of VMT treatments with a follow-up period of 6 months.

Main results and the role of chance: We expect the RCT to end in March 2023, and the results of this trial will be presented at the ESHRE annual meeting . If we can show engraftment of a eubiotic microbiome transplant without the use of pre-treatment with antibiotics it could be a potential treatment of vaginal dysbiosis.

Limitations, reasons for caution: As this is the first VMT without antibiotic pretreatment we did not have reliable data for our power calculation and a negative result may be due to lack of statistical power.

Wider implications of the findings: Effective treatments for vaginal dysbiosis are urgently needed and VMT may be one such treatment strategy.

Trial registration number: NCT04855006