INFORMATION FORM

TO PARTICIPATE IN THE STUDY

Version 2 – 13th May 2024

Integrated genetic and functional analysis of the influence of menstrual products on intimate female health (Luna Study)

Research study at the University Hospital Antwerp and the University of Antwerp, in a collaboration between the Faculty of Sciences, Department of Bioengineering and the Faculty of Medicine and Health Sciences

Necessary information for your decision to participate

Dear participant,

We would like to ask your permission to participate in this study about the influence of menstrual products on the microorganisms that live on and in your body (this is what we call the microbiome), and its influence on your immune system (this is our natural defense system). The vaginal microbiome is mainly dominated by lactobacilli, which are bacteria that produce lactic acid and keep the vagina healthy. Vaginal infections (or a poor balance of the microbiome) are a major and underestimated problem in today's society because of the taboo that still surrounds it. The vaginal microbiome is very important for our health, for healthy pregnancies, against STIs (sexually transmitted infections) and other infections. These risks are a relevant global burden that urgently needs more scientific attention.

Several scientific studies have shown that our environment can affect our health and shape our microbiome and immune system over our lifetime. With the exception of a few studies, there are no studies that assess the relationship between the female microbiome and lifestyle factors. The existing studies tend to be very limited and do not focus on menstrual health. For example, there is very little scientific data on the use of menstrual products, even though they play a major role in the daily lives of women around the world.

Thus, the purpose of this study is to investigate the microbial composition of the intimate skin, in the vagina and in menstrual blood after the use of various menstrual products, as well as the impact on the immune system.

The ultimate goal of this study is to determine the microbiome by body region and establish risk factors for vaginal dysbiosis and examine microbial strains by body region.

This could make an important contribution to the development of menstrual products and help women make an informed choice regarding which product they prefer to use.

Course of the study

The studies are conducted at the University of Antwerp (UAntwerpen), within the Department of Bioengineering in the Laboratory of Applied Microbiology and Biotechnology under the direction of Prof. Sarah Lebeer, in collaboration with Prof. Veronique Verhoeven (Department of Family Medicine and Population health, FAMPOP) as the responsible physician.

The current study includes two target groups, one of which has a natural cycle (with or without a copper IUD) and the other group takes the combined pill. Everyone registered will complete a comprehensive questionnaire regarding both medical history and lifestyle prior to sample collection. The questionnaire will take about 30 minutes to complete. Based on this extensive questionnaire, a selection of 100 participants will be made to participate in the effective intervention study. These participants will be asked to wear a different menstrual product (tampon, sanitary towel, menstrual cup and 2 types of menstrual underwear) during a period of 5 menstrual cycles and to fill out questionnaires at 3 different moments (before, during and after menstruation) and to collect samples themselves so that the microbial composition can be monitored, this is a swab (swab) from the vagina (internal intimate parts) at each sampling moment, vulva (external intimate parts) and skin of the groin area. Menstrual blood is collected directly through the menstrual cup by dipping a swab in the collected blood,or extracted by the laboratory from a worn product (tampon, sanitary napkin or menstrual underwear). All samples will be brought once a month after the last sample point to the lab (Campus Groenenborger, Groenenborgerlaan 171 2020 Berchem Belgium) by the participant, using the provided ice-packs and storage container. If this is not possible, a possibility is pick-up by a staff-member at the participants' house or workplace. This is necessary to ensure sample quality during transport. Microbial genetic material will then be isolated that will be used to determine the microbial community. These samples will also be used to isolate healthy vaginal bacteria (lactobacilli) and other beneficial microorganisms to study their specific properties, which may depend on the area where they are found. In addition to the identification and quantification of specific microorganisms, what metabolites are produced by these microorganisms and in what concentration will also be studied. Also to be studied will be the interaction between immune (or blood) cells of the female reproductive system and the vaginal microbiome.

Benefits of the study

These sample collections are easy to perform and do not hurt. You help the research towards improved knowledge about the impact of daily used products on female sexual and reproductive health, as well as the health of their children. For yourself, it provides no additional results discussion or treatment. We like to communicate our results to our

participants through the Isala project website (isala.be) or through our social media channels (Isala_Uantwerp), this way we keep women informed about new discoveries and scientifically validated information regarding intimate female health.

Cost and reimbursement.

There will be no charge for participation in this study as all services are free. No compensation will be provided for the volunteers. Menstrual products and normal underwear will be provided throughout the study, therefore, the products that do not need to be sent as samples may be kept by the participant (e.g. menstrual cup and menstrual underwear). In addition, each participant will receive individual information on the composition of their microbiome through the Isala project website (isala.be).

Possible risks.

There is no risk or discomfort associated with sample collection. This study was approved by the independent Ethics Committee of the University Hospital of Antwerp and the University of Antwerp. All volunteers are insured according to article 29 of the law of May 7, 2004 (UZA insurance contract). Feasibility, significance, safety and compliance with international recommendations were evaluated by this Committee. The nature of the research also means that no treatment can or will be instituted. Indeed, the study as well as the techniques used have not been appointed for diagnostic research but only for scientific research.

Confidentiality

All personal data and information that you will provide through the questionnaires during the study will be kept confidential. In addition, the processing of the personal data you provide will be in accordance with the General Data Protection Regulation (also known as GDPR) and relevant Belgian legislation1. During the course of the study, your samples and associated results will be linked to a personal code. By working with pseudonymization, where your personal data are converted to encrypted data via a code, we can provide you with personalized feedback on your microbiome profile with additional interpretation at a later stage. The key from the code to the link to your personal data is password protected and only available to the responsible physician, principal investigator and performing researchers. For the careful storage of the samples, we cooperate with the University Hospital Antwerp and the Biobank Antwerp. If the results of this study are published in a report or scientific journal or made public in any other way, you will never be mentioned by name.

In the context of facilitating further scientific research, including in function of the ERC StG project Lacto-Be (852600), we will further process the information and personal data collected about you. We hereby guarantee that these additional processing operations are compatible with the original purposes for which the data you provided were collected as part of this study. Further processing of the samples and collected information for

secondary scientific research is possible. Furthermore, this may include possible follow-up research with more (commercial) valorization objectives such as the development of new diagnostics and therapeutics. In this process, the data will always be used pseudonymously.

The University of Antwerp has a data protection officer. If you have any questions or concerns regarding the protection of your personal data, please send a written inquiry to Koen Pepermans, Sint-Jacobstraat 2, 2000 Antwerp, Belgium or privacy@uantwerpen.be.

Biobank

All human body material originating from the University Hospital Antwerp (UZA) and the University of Antwerp will be processed, coded and kept for scientific research purposes in the Biobank Antwerp according to the Royal Decree of January 9, 2018.

Voluntary participation / Withdrawal of participation from the study.

You are voluntarily participating in the study. You may also decide not to participate in the study and you may withdraw from the study at any time, even if you have signed this form. You can do this by contacting the principal investigators in writing (via email or letter). Due to the nature of the study, it is not possible to destroy samples already donated, so as not to compromise the statistical power of the study.

Right to information, inspection, correction and deletion

You have the right to request information about the procedures and the research project described. All reasonable requests for information will be answered by the principal investigator to the best of his or her ability. If there are significant changes in the procedures, risks or benefits of this study you will be informed. Furthermore, you also have the right to access your personal results (questionnaire data and analysis results). You also have the right to correct or delete your personal data. You can do this by contacting the principal investigators in writing (via e-mail or letter).

Statement of the principal investigator

The principal investigators Prof. Sarah Lebeer and Prof. Veronique Verhoeven are responsible to conduct this research program according to the conditions described in this document.

Responsible physician

Prof. Dr. Veronique Verhoeven, Department of Family Medicine and Population Health, Doornstraat 331, 2610 Wilrijk, Tel: 03/265 25 18

Responsible microbiologist

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