Request to participate in medical research:

Title of the research project

Study on mixed infections with chlamydia and gonococci

Dear study participant

We would like to ask you whether you would be willing to participate in our research project.
You have been diagnosed with chlamydia and/or gonococci. We are conducting the following study to find out more about these diseases and to be able to better prevent them in the future.
Your participation is voluntary. All data collected in this project is subject to strict data protection regulations. The research project is being carried out as part of a study that is partially funded by the Federal Office of Public Health (FOPH), the Swiss National Science Foundation and the company Sefunda AG. If you are interested, you can find information about the results at www.swissprepared.ch.

We will explain the most important points to you and answer your questions. So that you can already get an idea, here is the most important information first. Further detailed information will follow.

Why are we conducting this research project?

- In our research project, we want to find out whether the pathogen load of chlamydia and gonococci is greater in mixed infections than in infections with only one of the two pathogens.

What do i have to do if I take part? – What will happen to me if I take part?

- Form of participation: If you decide to participate, you must take 2 rectal swab samples.
- Procedure: These swab samples will then be tested for chlamydia and gonococci in the laboratory.
- Duration: The swab collection only takes a few minutes and can be done directly at the Checkpoint Clinic Zurich.
- Number and cost of visits: This is a one-off sample collection. It takes place either as part of the SwissPrEPared study or as part of your other visits at Checkpoint Zurich and only takes a few minutes.

What are the benefits and risks associated with this study?

Benefit

- There is no direct benefit for you if you take part in this research project. The study serves to gain knowledge in research.
- Your participation will help future patients because the project can improve our understanding of mixed infections with chlamydia and gonococci.

Risk and Exposure

- There are no risks.

By signing at the end of the document, you confirm that you are participating voluntarily and that you have understood the contents of the entire document.

Detailed Information

1. Aim and selection

With this study, we want to investigate whether the pathogen load is higher in mixed infections of chlamydia AND gonococci than in single infections, i.e. when only chlamydia OR gonococci alone occur. In our study, we assume that the two pathogens influence each other, i.e. they favour each other and the pathogen load is greater.

We are asking you because men who have sex with men who have tested positive for chlamydia (*Chlamydia trachomatis*) and/or gonococcus (*Neisseria gonorrhoeae*, the causative agent of gonorrhoea) can participate.

2. General information

- We still know little about the pathogen load of chlamydia and gonococci in mixed infections. These two pathogens often occur together and can be found in the rectum, urethra and pharynx. Both pathogens are often found simultaneously in the rectum, but it remains unclear how chlamydia and gonococci influence each other.
- We would therefore like to find out whether the pathogen load is higher in mixed infections of chlamydia AND gonococci than in single infections, i.e. when only chlamydia OR gonococci occur alone.
- If you participate, you will take 2 rectal swab samples from yourself, which will then be analysed further in the laboratory.
- This research study will only take place at Checkpoint Zurich (monocentric study).
- We are conducting this study in accordance with Swiss law. We also observe all internationally recognized guidelines. The responsible ethics committee has reviewed and approved the study.

3. Procedure

- The one-time sample collection takes place as part of the treatment of a chlamydia or gonococcal infection. The sample collection is carried out by the study participant and takes place at Checkpoint Zurich. After instruction by the investigator, the study participant takes 2 swab samples from the rectum in the toilet. This procedure takes a few minutes and is a one-time procedure. Both swabs are further examined in the laboratory for chlamydia and gonococci using molecular methods and culture.
- This study tests for the 2 reportable infectious agents' chlamydia (*Chlamydia trachomatis*) and/or gonococci (*Neisseria gonorrhoeae*, the pathogen that causes gonorrhoea). Any positive results are reported to the BAG/FOPH.

4. Benefit

You will not personally benefit from participating in the study.

5. Voluntary participation and obligations

Your participation is voluntary. If you do not wish to take part in this study or wish to withdraw your participation later, you do not have to justify this. Your medical treatment/support is guaranteed regardless of your decision.

6. Risks and burdens

No risks or particular burdens are to be expected from the collection of the rectal swab samples .

7. Results

There are final results of the entire study as objective, which will be published anonymously in scientific journals and on www.swissprepared.ch.

8. Confidentiality of data and samples
For this study, your personal and health data will be collected and processed, partly in automated form. Your data will be encrypted during data collection. Encryption means that all reference data that could identify you (name, date of birth, etc.) will be deleted and replaced by a code. People who do not have access to this key list cannot draw any conclusions about you. The key list always remains at Checkpoint Zurich.

Only very few specialists will see your unencrypted data and only to fulfill tasks within the scope of the study. These persons are bound to confidentiality. As a participant, you have the right to view your data.

All data protection regulations are strictly adhered to. It is possible that your data may have to be transmitted in encrypted form, for example for publication, and may be made available to other researchers. This study may be reviewed by the responsible ethics committee. The investigator must then disclose your data for such reviews. All must maintain absolute confidentiality.

9. Withdrawal
You can withdraw from the study at any time. In this case, however, the data and samples collected up to that point will still be analyzed anonymously. The samples will be destroyed after evaluation.

10. Compensation
If you participate in this study, you will not receive any compensation.

11. Liability
If you suffer any damage as a result of participating in this study, please contact the investigator.

12. Funding
The study is mainly financed by the Federal Office of Public Health (FOPH/BAG), and the Swiss National Science Foundation.

13. Contact person(s)
You may ask questions about participating in the study at any time. If you have any uncertainties or emergencies that arise during or after the study, please contact:

Name oft he investigator:
Dr. Benjamin Hans Hampel
Limmatstrasse 25
8005 Zürich
Phone: +41 44 455 59 10
Benjamin.Hampel@cpzh.ch

Declaration of consent

Written declaration of consent for participation in a clinical study
Please read this form carefully. Please ask if there is anything you do not understand or would like to know. Your written consent is required for participation.

BASEC-Number (after submission):	2021-01802
Title of the study (scientific and lay language):	Elucidating the pathogenic interplay between *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Shedding light on increased susceptibility to infection and treatment failure? Study on mixed infections with chlamydia and gonococci
Responsible Institution (Sponsor with Adress):	Prof. Nicole Borel Institut für Veterinärpathologie Universität Zürich Winterthurerstrasse 268 8057 Zürich
Place of implementation:	Checkpoint Zürich
Investigator at the study site: Surname and first name in uppercase:	
Participant: Surname and first name in uppercase: Date of birth:	

- I have been informed verbally and in writing by the undersigned investigator about the purpose, the course of the study, about possible advantages and disadvantages as well as about possible risks.
- I am taking part in this study voluntarily and accept the content of the written information given to me. I have had sufficient time to make my decision.
- My questions in connection with participation in this study have been answered. I will keep the written information and receive a copy of my written informed consent.
- I agree that the responsible experts of the relevant ethics committee may inspect my unencrypted data for testing and monitoring purposes, but under strict confidentiality.
- I know that my health-related and personal data (and samples) can only be passed on in encrypted form for research purposes for this study. The sponsor guarantees that data protection according to Swiss standards will be observed.
- I can withdraw from participation in the study at any time and without giving reasons. My further medical treatment is guaranteed regardless of my participation in the study. The data and samples collected up to the time of withdrawal will still be analyzed as part of the study.

Place, Date	Signature oft he participant

Confirmation of the investigator: I hereby confirm that I have explained the nature, significance and scope of the study to this participant. I confirm that I will fulfill all obligations in connection with this study in accordance with applicable Swiss law. If, during the course of the study, I become aware of any aspects that could influence the participant's willingness to take part in the study, I will inform him/her immediately.

Place, Date	Place, date Surname and first name of the investigator in uppercase Signature of the investigator