Title of the research project

Study on mixed infections with chlamydia and gonorrhoeae

Dear SwissPrEPared Participant

We would like to invite you to participate in our research project.

You have been diagnosed with chlamydia and/or gonorrhoea. We are interested to learn more about these 2 infections and how to prevent them in the future. This is why we started the present study.

Your participation in this study is optional and entirely voluntary. All data collected during this project are handled completely confidentially. This research project is part of a study financed, in part, by the Swiss National Science Foundation and the company Sefunda AG. Please find further information about the study results on: www.swissprepared.ch.

During your visit, we will explain to you the most important points of the study and answer any questions you might have. Here, we summarize the most important facts about the study. This is followed by more detailed information.

What is the reason for conducting this research project?

- In our study, we will investigate if the quantity of bacteria is higher in co-infection with chlamydia and gonorrhoea than with single infection with either of these two bacteria.

What is the participation procedure? What do I have to do?

- Participation: If you agree to participate in the study, you will self-collect two rectal swab samples.
- Procedure: The swabs samples will be tested for chlamydia and gonorrhoea in the laboratory.
- Duration: The sample collection will only take a few minutes and will take place at the Checkpoint clinic, here in Zurich.
- Number content of visits: there will be a single sample collection. This sampling is part of the SwissPrEPared study and will only take a few minutes.

Which benefits or risks are associated with this study?

Benefit

- You will not have any direct benefit from participating in this study. This study aims to gain new research knowledge.
- Your participation will be beneficial for future patients. This project will enhance the understanding about co-infections between chlamydia and gonorrhoea.

Potential risk and burden

- There is no obvious risk.

With your signature at the end of this document, you confirm your voluntary participation in this study. You also confirm that you have understood the content of the entire document.

Detailed information

1. Goal of the study

In this study, we will investigate if the quantity of bacteria during a co-infection with chlamydia and gonorrhoea is higher than with a single infection with either bacteria. We hypothesize that these bacteria interact with each other synergistically, resulting in a higher quantity of bacteria during co-infection.

Men who have sex with men already participating in the SwissPrEPared study and having a positive test result for chlamydia (caused by *Chlamydia trachomatis*) and/or gonorrhoea (caused by *Neisseria gonorrhoeae*) are eligible to participate in this study.

2. General information

- The knowledge about pathogen load during co-infections with chlamydia and gonorrhoea is limited. Both pathogens often occur together and infections can be found at the rectal site, the urethra and the pharynx. Both pathogens can be found simultaneously at the rectal site but it remains unclear how they interact with each other.
- We would like to know if the pathogen load is higher in co-infections with chlamydia and gonorrhoea compared to a single infection with either of these 2 pathogens.
- If you participate in this study, you will self-collect 2 rectal swabs which will be further analyzed in the laboratory.
- This study will take place only at one site (monocentric study): Checkpoint Zürich.
- The duration of the study will be similar to the overarching SwissPrEPared study. Our study participants will be recruited at the Checkpoint Zürich. The approximate study participant number is estimated at 1200.
- We conduct this study according to the Swiss law. We further respect the international approved guidelines. This study is approved by the ethics commission of the canton of Zurich.

3. Procedure

- There will be a single sampling before the treatment of an infection with chlamydia and/or gonorrhoea, which have been diagnosed as part of the SwissPrEPared study.
- The sampling will consist of two self-taken swabs at the Checkpoint clinic in Zürich. The physician will guide you on how to take the sample. The sampling consists of 2 rectal swabs which will be self-taken in the toilet of the clinic. This will take only few minutes and will take place only once. Both rectal swab samples will be further tested for chlamydia and gonorrhoea in the laboratory, using molecular testing methods and culture.
- In this study, 2 notifiable pathogens will be investigated: chlamydia (*Chlamydia trachomatis*) and/or gonorrhoea (*Neisseria gonorrhoeae*). Any positive result will be communicated to the Swiss Federal Office of Public Health (FOPH, BAG) as part of the SwissPrEPared study.

4. Benefit

You will not have any direct benefit from participating in this study.

5. Voluntariness and responsibilities

You participation is entirely voluntary. You will not need any reason to refuse participation in this study or to withdraw from the study. Your medical treatment/support does not depend on study participation.

6. Risk and burden

No risks or burden are expected during collection of rectal swab samples.

7. Results

The end results of this study will be published on www.swissprepared.ch.

8. Confidentiality on data and samples

During this study, personal and health data will be collected and processed in an anonymized manner. Your data will get encoded during data collection. Encoded data means that all data which could reveal your identity (name, date of birth, etc.) will be deleted and replaced by a code. Persons without access to the coded list cannot retrieve your personal data. The coded list remains at the Checkpoint clinic in Zürich. Only a few experts will have access to the coded list to fulfill necessary tasks within this study. These persons are obliged to abide by medical confidentiality. You as a participant have the right to access your data.

All requirements for data protection will be followed. It is possible that your data will be provided to other researchers for publication or other purposes, but the data will remain anonymized. This study may be checked by the respective ethics commission. The physician will disclose your data for such controls. Confidentiality will remain secure under all circumstances.

9. Withdrawal

You can withdraw from the study, at any time. All data and samples collected until withdrawal will be still part of the study but in an anonymized manner. All samples will be destroyed after analysis.

10. Compensation

You will not receive any compensation from participation in this study.

11. Liability

In case you suffer any loss from the participation of this study, please contact the physician at the study center.

12. Financing

The study is financed by the Swiss National Science Foundation and the company Sefunda AG.

13. Contact person/s

You can also ask questions related to your study participation. In case of questions or emergencies during or after the study, please contact:

Name of the physician:
Dr. Benjamin Hans Hampel
Checkpoint Zürich
Konradstrasse 1
8005 Zürich
Phone: +41 44 455 59 10
Benjamin.Hampel@cpzh.ch

Informed consent

Written informed consent to confirm the participation in this study
Please read this form and ask any questions if you do not understand the content or if you would like to know more about the study. Your written consent is necessary to participate in this study.

BASEC-number:	2021-01802
Title of study (scientific and colloquial 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 gonorrhoea
Responsible institution (Sponsor with address):	Prof. Nicole Borel Institute of Veterinary Pathology University of Zürich Winterthurerstrasse 268 8057 Zürich
Place of study:	Checkpoint Zürich
Physician at the study center: First and second name in block letters:	
Participant: First and second name in block letters: Date of birth:	

- I was informed, orally and in writing about the goals, the workflow and potential advantages and disadvantages as well as potential risks of the study by the signing physician.
- I participate voluntarily in this study and confirm that I understand the content of this informed consent. I have had enough time to take the decision about my participation in this study.
- My questions related to participation in this study have been answered. I will keep the written information and will receive a copy of the signed informed consent.
- I agree that the experts of the referring ethics commission can have insight into my non-anonymized data for control purposes. However, confidentiality is guaranteed.
- I am aware that my personal and health data (and samples) are only forwarded in an anonymized form for research purposes of this study. The sponsor confirms that data protection according to Swiss standards is guaranteed.
- I can always, at any time, refrain from study participation without providing specific reasons. My further medical treatment is also secured without participation in the study. All data and samples collected up to withdrawal will be still used within the context of the study.
- I agree that remaining samples can be provided to the company Sefunda AG for validation purposes but will remained anonymized. ☐Yes ☐No

Place, date	Signature of the participant

Confirmation of the physician: I hereby confirm to have informed the participant about the type, significance and extent of the study. I confirm compliance with all rules according to Swiss law. I will immediately inform the study participant in case of study circumstances that could influence their decision to participate in this study.

Place, date	First and second name of the physician in block letters Signature of the physician