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# Comparison of different antibiotics in patients undergoing prostate biopsy

**Submission date**
24/08/2023

**Recruitment status**
No longer recruiting

**Registration date**
26/08/2023

**Overall study status**
Completed

**Last Edited**
15/01/2024

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
In this research project, we're looking at a specific medical procedure called transrectal prostate biopsy (PB), which involves taking samples from the prostate gland to check for potential issues. Our main goal is to figure out how different short-term preventive antibiotics used during this procedure affect the chances of getting infections, considering the conditions in our local medical setup. This is connected to a concern about the safety of a type of antibiotics called fluoroquinolones that are commonly used for this purpose. Since these antibiotics might have some risky side effects, we want to find out if there are better ways to prevent infections after the biopsy. By studying this carefully, we hope to learn which approach works best and is safest for patients undergoing this procedure, and this could help doctors make better decisions for their patients.

Who can participate?
Patients who will undergo transrectal ultrasound-guided PB will be included in the study.

What does the study involve?
In this study, we're going to divide the patients into three groups randomly, based on the way they'll take antibiotics before a prostate biopsy. About 1 to 2 weeks before the biopsy, we'll gently swipe the inside of their rectum to see if any harmful bacteria are there. After the biopsy, we'll keep an eye on them for a month to see if any problems or complications come up. We want to see which antibiotic method works better at preventing issues, and we're also checking the bacteria in the rectum to understand more about what might cause infections.

What are the possible benefits and risks of participating?
The benefit is in a short-term regimen of antibiotic prophylaxis with potential minimization of side effects. The risk is the possible occurrence of infectious complications requiring further treatment or hospitalization.

Where is the study run from?
University Hospital Brno (Czech Republic)

When is the study starting and how long is it expected to run for?
November 2020 to January 2023

Who is funding the study?
The work is supported by Ministry of Health, Czech Republic - conceptual development of research organization (FNBr, 65269705).

Who is the main contact?
Ass. prof. Michal Fedorko, fedorko.michal@fnbrno.cz
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# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
012020

## Study information

### Scientific Title
Comparison of efficacy of three different regimens of Short-term ANtibiotic prophylaxis in TRransrectal prostate bIOpsy

### Acronym
SANTRIO

### Study objectives
Short-term fosfomycin trometamol is an effective alternative to ciprofloxacin-based regimens.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 04/11/2020, Ethics Committee of University Hospital Brno (Jihlavská 20, Brno, 62500, Czech Republic; +42 0532232805; rosenbaumova.lenka@fnbrno.cz), ref: 05-041120/EK

### Study design
Single-center interventional randomized parallel trial

### Primary study design
Interventional

### Secondary study design
Randomised parallel trial

### Study setting(s)
Hospital

### Study type(s)
Safety, Efficacy

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

### Health condition(s) or problem(s) studied

Prevention of infectious complications in patients undergiong transrectal prostate biopsy

### Interventions
Patients who will undergo transrectal prostate biopsy will be randomized according to the regimen of antibiotic prophylaxis into 3 groups:
1. Fosfomycin trometanol 3g before the procedure + ciprofloxacin 500mg 2 hours before the procedure
2. Fosfomycin trometamol 3g before and 24 hours after the procedure
3. Ciprofloxacin 500mg 12 hours abd 2 hours before the procedure and 12 hours after the procedure.

Follow-up of study arms 4-6 weeks

Randomization based on the month of study based on the application for ordering patients for procedures.

### Intervention Type
Drug

### Pharmaceutical study type(s)
Not Applicable

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Fosfomycin trometamol, ciprofloxacin

### Primary outcome measure
The occurrence of infectious complications during the follow-up period will be assessed during a personal follow-up visit within 4-6 weeks after the procedure. In case of symptoms of infectious complications, these will be recorded at any time during the follow-up period

### Secondary outcome measures
Evidence of adverse events of short-term antibiotic prophylaxis during the follow-up period will be assessed during a personal follow-up visit within 4-6 weeks after the procedure

### Overall study start date
04/11/2020

### Completion date
31/01/2023

## Eligibility

### Key inclusion criteria
Patients indicated for transrectal prostate biopsy based on PSA and/or PHI level, digital rectal examination finding of magnetic resonance finding.

### Participant type(s)

Patient

**Age group**
Adult

**Lower age limit**
30 Years

**Upper age limit**
99 Years

**Sex**
Male

**Target number of participants**
600

**Total final enrolment**
550

**Key exclusion criteria**
Allergy to any of the antibiotic or local anesthetic, indwelling urinary catheter or epicystostomy, patients requiring other antibiotic prophylaxis due to other medical condition.

**Date of first enrolment**
01/01/2021

**Date of final enrolment**
31/12/2022

# Locations

**Countries of recruitment**
Czech Republic

**Study participating centre**
**University Hospital Brno**
Jihlavská 20
Brno
Czech Republic
62500

# Sponsor information

**Organisation**

University Hospital Brno

### Sponsor details
Jihlavska 20
Brno
Czech Republic
62500
+420532233860
fnbrno@fnbrno.cz

### Sponsor type
Hospital/treatment centre

### Website
http://www.fnbrno.cz/en/

### ROR
https://ror.org/00qq1fp34

## Funder(s)

### Funder type
Government

### Funder Name
Ministry of Health, Czech Republic

## Results and Publications

### Publication and dissemination plan
Publication in a high-impact peer-reviewed journal. Presentation of the results at national scientific meetings.

### Intention to publish date
01/03/2024

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Michal Fedorko (fedorko.michal@fnbrno.cz).

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Results article | 12/01/2024 | 15/01/2024 | Yes | No |