

Comparison of different antibiotics in patients undergoing prostate biopsy

Submission date 24/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/08/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/01/2024	Condition category Infections and Infestations	<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

012020

Study information

Scientific Title

Comparison of efficacy of three different regimens of Short-term ANTibiotic prophylaxis in TRansrectal 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

Study type(s)

Safety, Efficacy

Health condition(s) or problem(s) studied

Prevention of infectious complications in patients undergoing 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 trometamol 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 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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fosfomycin trometamol, ciprofloxacin

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

30 years

Upper age limit

99 years

Sex

Male

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

ROR

<https://ror.org/00qq1fp34>

Funder(s)**Funder type**

Government

Funder Name

Ministry of Health, Czech Republic

Results and Publications

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