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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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Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single-center interventional randomized parallel trial

Study type(s)
Safety, Efficacy

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

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