Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of antibiotic therapy on the results of biopsy in asymptomatic men older than 40 years of age with PSA above 4 ng/ml

Protocol summary

Study aim

The effect of antibiotic therapy on the results of biopsy in asymptomatic men older than 40 years old with PSA above 4 ng/ml

Design

This study is a randomized clinical trial with control group and parallel group design

Settings and conduct

This study is being conducted at Shahid Doctor Rahnamoon Hospital in Yazd City. Eighty Patients older than 40 years of age with prostate-specific antigen (PSA) in the range of 4-15 ng/ml are enrolled based on the criteria for entering the study and are randomly assigned to intervention(Antibiotic therapy) and control (No drug treatment) groups using sealed envelopes. Blinding is not done. In all patients, after 1 month, the PSA level is measured, and patients with PSA level above 4 ng/ml will undergo a standard biopsy(12-core) according to patient's age and PSA density. The biopsy samples will be read and recorded by a pathologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 40 years of age Referring to the Urology Clinic of Shahid Doctor Rahnemoon Hospital in Yazd, Iran with prostate-specific antigen (PSA) in the range of 4-15 ng/ml with normal digital rectal examination (DRE) and without Irritative and obstructive urinary symptoms. Non-inclusion criteria: Patients undergoing rectal biopsy (TRUS) during the past month, who have ejaculation in the past 28 hours, Patients who have undergone urological surgeries during the past six months, with a history of prostate cancer or clinical and laboratory evidence and with a history of taking 5-alpha-blockers such as Finasteride in the past six weeks do not enter the study.

Intervention groups

Intervention group: Patients will undergo antibiotic therapy (Ciprofloxacin tablets 500 mg every 12 hours for 4 weeks). Control group: Patients won't receive any medication.

Main outcome variables

PSA level ;Prostate biopsy results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180915041037N1**
Registration date: **2018-11-11, 1397/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-11, 1397/08/20**
Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name
Samad Zare
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3312 2540
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of antibiotic therapy on the results of biopsy in asymptomatic men older than 40 years of age with PSA above 4 ng/ml

Public title
The effect of antibiotic therapy on the results of biopsy in men

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 40 years of age with prostate-specific antigen (PSA) in the range of 4-15 ng/ml Patients with normal digital rectal examination (DRE) Patients without Irritative and obstructive urinary symptoms Patients with informed consent
Exclusion criteria:
Patients undergoing rectal biopsy (TRUS) during the past month. Patients who have ejaculation in the past 28 hours. Patients who have undergone urological surgeries during the past six months. Patients with a history of prostate cancer or clinical and laboratory evidence Patients with a history of taking 5-alpha-blockers such as Finasteride in the past six weeks

Age
From **40 years** old to **70 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are randomly assigned to intervention and control groups using sealed envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
Street address
Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916978477

Approval date
2018-10-27, 1397/08/05

Ethics committee reference number
IR.SSU.MEDICINE.REC.1397.096

Health conditions studied

1

Description of health condition studied
Prostate Cancer

ICD-10 code
C61

ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
PSA levels above 4 ng / ml

Timepoint
One month after referring to the specialist

Method of measurement
Blood test

Secondary outcomes

1

Description
Biopsy results

Timepoint
One month after referring to the specialist

Method of measurement
Standard biopsy (12-core)

Intervention groups

1

Description
Intervention group: Patients will undergo antibiotic therapy (Ciprofloxacin tablets 500 mg every 12 hours for 4 weeks)

Category
Treatment - Drugs

2

Description
Control group: Patients won't undergo any medication.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Doctor Rahnemoon Hospital
Full name of responsible person
Hadi Maleki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
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Position
Resident
Latest degree
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available