

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 Rahnamoon 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

Email address

s.zare@ssu.ac.ir

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 Rahneemoon Hospital

Full name of responsible person

Hadi Maleki

Street address

Farrokhi Street

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8913893111

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hadi.maleki88@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Hadi Maleki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Samd Zare

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Associate professor

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Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hadi Maleki

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Urology

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Email

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