

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy in patients suspicious for prostate cancer and comparison with control group

Protocol summary

Summary

The aim of this clinical trial is to evaluate the effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy. 120 patients who are referred to the Urology department of Imam Reza Hospital, Mashhad due to abnormal prostate in digital rectal exam (DRE) or increase in prostate specific antigen (PSA) for biopsy of the prostate are divided randomly into two equal groups. After obtaining informed consent, the case group receive an intrarectal mixture of povidone-iodine and lidocaine gel before performing biopsy, while the control group receive only lidocaine gel. Rectal swab specimens obtain before and after biopsy and will send for culture. Patients are followed weekly up to 30 days for possible signs of infection or hospital readmission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092429935N1**
Registration date: **2017-11-13, 1396/08/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name

Seyedalireza Ghoreifinejadian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3885

Email address

ghoreifina@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-06-07, 1396/03/17

Expected recruitment end date

2018-11-29, 1397/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy in patients suspicious for prostate cancer and comparison with control group

Public title

The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Men who refer to the Urology department of Imam Reza Hospital, Mashhad due to abnormal prostate in digital rectal exam (DRE) or increase in prostate specific antigen (PSA) for biopsy of the prostate , Obtaining informed consent
Exclusion Criteria: No informed consent

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Daneshgah St

City

Mashhad

Postal code

Approval date

2017-06-07, 1396/03/17

Ethics committee reference number

IR.MUMS.fm.REC.1395.645

Health conditions studied

1

Description of health condition studied

Acute prostatitis

ICD-10 code

N41.0

ICD-10 code description

Acute prostatitis

Primary outcomes

1

Description

infectious complications

Timepoint

every week to 30 days

Method of measurement

History and Physical exam

Secondary outcomes

1

Description

Rectal Culture

Timepoint

Before and after biopsy

Method of measurement

Rectal swab

Intervention groups

1

Description

Rectal enema with 50 cc mixture of Povidone-Iodine and lidocaine jelly before biopsy in case group

Category

Prevention

2

Description

Rectal enema with 50 cc lidocaine jelly before biopsy in control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Department, Imam Reza Hospital

Full name of responsible person

Seyedalireza Ghoreifinejadian

Street address

Urology Department, Imam Reza Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Eslami

Street address

Ghoreishi Building, Daneshgah Street

City

Mashhad

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source

100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Seyedalireza Ghoreifinejadian

Position
Assistant Professor of Urology

Other areas of specialty/work

Street address
Urology Department, Imam Reza Hospital

City
Mashhad

Postal code

Phone
+98 51 3858 3885

Fax

Email
ghoreifina@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Seyedalireza Ghoreifinejadian

Position
Assistant Professor of Urology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty