

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The assessment of effect of local antiseptic on UTI in the cases of transrectal ultrasound-guided prostate biopsy

Protocol summary

Summary

Purpose of study: The assessment of effect of betadine on prevention of UTI after prostate biopsy; Study design: interventional; Method: The patients will be randomized into two groups. 1- In interventional group Betadine Vaginal Gel 10% (Povidone Iodine; 80g) with Gavage Syringe is injected into the rectum and after 5 minutes prostate biopsy will be performed. 2- In control group patients will not receive betadine before prostate biopsy. 48h after the biopsy UA and UC will be obtained from patients and fever of the patients will be evaluated. The results of study in this two groups will be compared with together; Inclusion criteria: All patients that candidate for transrectal ultrasound-guided prostate biopsy who referred to Shahid Hasheminejad Hospital; Exclusion criteria: Unable to follow-up patients; Presence of abnormal UA and UC before Prostate biopsy; Unable to use local antiseptic; Previous prostatectomy; Intervention: Drug (Betadine); Target sample size: 300; Primary outcome measure: Acute prostatitis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201038605N1**
Registration date: **2012-04-04, 1391/01/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-04, 1391/01/16

Registrant information

Name

Soodabeh Nikfarjam

Name of organization / entity

Tehran University of Medical Sciences (Paradise Hemmat)

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-10-06, 1391/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of effect of local antiseptic on UTI in the cases of transrectal ultrasound-guided prostate biopsy

Public title

The effect of betadine on prevention of UTI after prostate biopsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients that candidate for transrectal ultrasound-guided prostate biopsy who referred to Shahid Hasheminejad Hospital; Exclusion criteria: Unable to follow-up patients; Presence of abnormal UA and UC before Prostate biopsy; Unable to use local antiseptic; Previous prostatectomy

Age
No age limit
Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences (Paradise Hemmat)

Street address

Medical school, near Milad hospital, Shahid Hemmat freeway

City

Tehran

Postal code

-

Approval date

2011-03-13, 1389/12/22

Ethics committee reference number

1372

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

acute prostatitis

Timepoint

48 hours after intervention

Method of measurement

U/A+U/C+Temperature of body

Secondary outcomes

1

Description

nothing

Timepoint

nothing

Method of measurement

nothing

Intervention groups

1

Description

Control:In this group without injection of betadine in the rectum prostate biopsy will be performed

Category

N/A

2

Description

intervention: Betadine Vaginal Gel 10% (Povidone Iodine; 80 g) with Gavage Syringe is injected into the rectum and after 5 minutes prostate biopsy will be performed

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminejad Hospital

Full name of responsible person

Dr Seyed Morteza Bagheri, Radiologist

Street address

Shahid Valinejad avenue, The North of Vanak square, Vali Asr street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences (Pardise Hemmat)

Full name of responsible person

Dr Seyed Morteza Bagheri

Street address

Tehran University of Medical Sciences (Pardise Hemmat), near Milad Hospital, Shahid Hemmat freeway

City

Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences (Pardise Hemmat)

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**

Tehran University of Medical sciences (Pardise Hemmat)

Full name of responsible person

Soodabeh Nikfarjam

Position

Student of Radiology

Other areas of specialty/work**Street address**

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Web page address

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