

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of enema with iodine on infection rate after transrectal prostate biopsy in patients suspected of prostate cancer in Imam Reza Hospital during years 2016-2019

Protocol summary

Study aim

Study the effect of enema with iodine on infection rate after transrectal prostate biopsy in patients suspected of prostate cancer

Design

This study is a one-blinded clinical trial. The research population will be included all patients referred to the urology ward of Imam Reza Hospital in Kermanshah. 230 eligible patients will be selected conveniently and randomly assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at Imam Reza hospital of Kermanshah, is a one-blinded one that the data analyst is blind to the allocation of study groups. At the beginning of the study, the severity of pain, body temperature, and fever and chills were recorded in a checklist for each of the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients whose serum PSA levels have increased; age between 50-68 years Exclusion criteria: Patients with normal rectal tenderness

Intervention groups

The intervention group will receive 600 cc betadine with 100 cc lidocaine by injected into the rectum and after 5 minutes the prostate biopsy will be performed with the normal saline enema. The control group will not receive any intervention

Main outcome variables

Pain severity, body temperature

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N148**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **prospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-28, 1399/02/09

Expected recruitment end date

2020-07-30, 1399/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of enema with iodine on infection rate after transrectal prostate biopsy in patients suspected of prostate cancer in Imam Reza Hospital during years

2016-2019	Sciences
Public title Study the effect of enema with iodine on infection rate after transrectal prostate biopsy in patients suspected of prostate cancer	City Kermanshah
Purpose Treatment	Province Kermanshah
Inclusion/Exclusion criteria Inclusion criteria: Patients whose serum PSA levels have increased Age between 50-68years Exclusion criteria: Patients with normal rectal tenderness	Postal code 6715847141
Age From 50 years old to 68 years old	Approval date 2019-11-04, 1398/08/13
Gender Male	Ethics committee reference number ir.kums.rec.1398.785
Phase 2-3	
Groups that have been masked • Data analyser	Health conditions studied 1 Description of health condition studied acute prostatitis ICD-10 code N41.0 ICD-10 code description Acute prostatitis
Sample size Target sample size: 230	Primary outcomes 1 Description Pain severity Timepoint The beginning of the study and one day after the end of the intervention Method of measurement Using visual scale of pain (VAS)
Randomization (investigator's opinion) Randomized	2 Description Body temperature Timepoint The beginning of the study and one day after the end of the intervention Method of measurement Using a thermometer
Randomization description Using the random number table, patients are divided into three groups of 115. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the first intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the second intervention group.	Secondary outcomes empty
Blinding (investigator's opinion) Single blinded	Intervention groups 1 Description The intervention group will receive 600 cc betadine with 100 cc lidocaine by injected into the rectum and after 5 minutes the prostate biopsy will be performed with the normal saline enema. Category Treatment - Drugs
Blinding description In this study, data analysts is kept blind to the allocation of study groups.	
Placebo Not used	
Assignment Parallel	
Other design features	
Secondary Ids empty	
Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Kermanshah University of Medical Sciences Street address Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical	

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Description

The control group will not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Ramin Ardeshiri

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Ramin.ardeshiri100@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

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Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Ramin Ardeshiri

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Urology

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Emam Reza Hospital, Parastar Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farajolah Parhoudeh

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 15-day timeframe

Comments