

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of radiation cystitis treatment with intravesical instillation of hyaluronic acid (cystistat)

Protocol summary

Study aim

Evaluation of radiation cystitis treatment with intravesical instillation of hyaluronic acid (cystistat)

Design

In this single-blind randomized clinical trial, patients undergoing radiotherapy due to pelvic malignancies and have cystitis symptoms, were randomly assigned to two groups (at least 20) via sealed envelopes. In one group, 40 mg (50 cc) of cystistat were injected into the bladder with a vial of 2% lidocaine and one vial of heparin and in the other group cystistat was replaced with 50 cc normal saline, and the solution One hour is kept in the bladder. This solution is injected weekly for up to 4 weeks and then monthly for up to 2 months.

Settings and conduct

all patients in Shohada Tajrish hospital in Tehran that due to pelvis radiation suffered from radiation cystitis included in this one side blind(patients) study.through sealed envelope patients were randomized to two groups and the effect of intravesical acid hyaloronic and normal saline in remission of urinary symptoms was compared

Participants/Inclusion and exclusion criteria

Patients who underwent radiotherapy due to pelvic malignancies and developed with urinary symptoms like hematuria, frequency and chronic pelvic pain has evaluated and patients with history of BPH,neurological and neurosurgical disease,positive urine culture,diuretic drugs consumption has excluded

Intervention groups

in one group 40 milligram(50 cc) cystistat plus one vial of lidocain 2% and one vial of heparin and in the other group 50cc normal saline with one vial of lidocain 2%and one vial of heparin instilled into bladder via catheter and was held in bladder for one hour and this methods repeated for 4 weeks weekly then every month for two months

Main outcome variables

situation of radiation cystitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038788N1**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

Registration date

2018-04-27, 1397/02/07

Registrant information

Name

amirhossein rahavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

amirrahavian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of radiation cystitis treatment with intravesical instillation of hyaluronic acid (cystistat)

Public title

evaluation of acid hyaluronic on radiation cystitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients that underwent radiotherapy due to pelvic malignancies and developed with urinary problems such as hematuria, frequency, CPPS patients did not response to current treatment of cystitis

Exclusion criteria:

history of BPH positive urine culture history of neurologic and neurosurgery disease diuretic drugs consumption

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done from a computer-generated sequence(SAS software), concealed in sequentially numbered, sealed, opaque envelopes, and kept by the ward secretary

Blinding (investigator's opinion)

Single blinded

Blinding description

after explanation of study, all the participants and care providers are blind because patients divided to two groups by sealed envelopes and same intervention was done for both groups but with different material.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran Province, Tehran, District 1, Daneshjou Blvd.,

Shahid Beheshti University of Medical Sciences

City

Tehran

Province

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Postal code

1983969411

Approval date

2018-02-21, 1396/12/02

Ethics committee reference number

IR.SBMU.UNRC.1395.78

Health conditions studied**1****Description of health condition studied**

Radiation cystitis

ICD-10 code

N30.41

ICD-10 code description

Irradiation cystitis with hematuria

Primary outcomes**1****Description**

score of pelvic pain

Timepoint

before intervention and 3, 6 , 9 months after intervention

Method of measurement

visual analogue scale to measure pain

2**Description**

urinary frequency

Timepoint

before intervention and 3, 6 , 9 months after intervention

Method of measurement

International Prostate Symptom Score(IPSS)

Secondary outcomes**1****Description**

Quality Of Life

Timepoint

before intervention and 3, 6 and 9 months after intervention

Method of measurement

King's Health Quality of Life Questionnaire

Intervention groups**1****Description**

Intervention group: in this group 40 mg(50 cc) cystistat

+one vial of lidocaine 2% + one vial of heparin instilled into bladder and reserved one hour in bladder. this solution instilled for four weeks weekly and then monthly for two months

Category

Treatment - Drugs

2**Description**

Control group: in this group 50 cc normal saline +one vial of lidocaine 2% + one vial of heparin instilled into bladder and reserved one hour in bladder. this solution instilled for four weeks weekly and then monthly for two months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Tajrish hospital

Full name of responsible person

Amirhossein Rahavian

Street address

Shohada Tajrish Hospital, Shahrdari Ave., Tajrish Square, Tehran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Urology and Nephrology Research Center Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Basiri

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

Yes

Title of funding source

Urology and Nephrology Research Center Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhossein Rahavian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Farzad Allame

Position

Associate Professor

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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