Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 envelops. 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 envelops 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
Tehran
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, Teharn

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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

Street address

Urology & Nephrology Research Center, No 103 9th Boustan. , Pasdaran Ave. , Tehran, I.R. Iran

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info@unrc.ir

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
Other areas of specialty/work
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Person responsible for updating data

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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