Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Treatment of interstitial cystitis; clinical effectiveness of hydrodistention with intravesical hyaluronic acid (cystistat®) over hydrodistention alone

Protocol summary

Study aim

We compared the therapeutic effects of bladder hydrodistention alone or together with intravesical cystistat (40mg of sodium hyaluronate in a 50ml vial) in the treatment of interstitial cystitis.

Design

A randomized controlled trial with blinded outcome assessment.The patients were allocated to the intervention (n=12) and control (n=12) groups based on the randomized computer assignment list.

Settings and conduct

This study was conducted in Urology Clinic of Imam Reza Hospital of Mashhad in 2017. Twenty-four female interstitial cystitis patients were selected using clinical examinations and the O`Leary-Sant questionnaire, which was also used for evaluating the effects of the treatment. all the patients filled O`leary saint questionnaire at the baseline, one week, one month and three months after treatment. PASS software was used for generating the random assignment list. The researcher who evaluated the questionnaires and the statistical analyzer were blinded but the doctor and the patients were aware of treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women over 18 years old with intravesical cystitis were included. Exclusion criteria: Patients with a history of other diseases related to the urogenital system, cyclophosphamide use, abdomen or pelvis radiotherapy, and urination frequency less than 8 times a day were excluded from the study.

Intervention groups

Intervention group: Hydrodistention was performed under general anesthesia for 8 minutes. Cystistat® produced by Mylan company was infused into the bladder through a catheter. it was kept in the bladder for 30 minutes, then drained by urinating. This procedure was done weekly for four weeks, then monthly until two months later. Control group: The control group underwent hydrodistention with the same procedure as the intervention group.

Main outcome variables

urgency, frequency, nocturia, dysuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130811014330N5**
Registration date: **2018-11-29, 1397/09/08**
Registration timing: **retrospective**

Last update: **2018-11-29, 1397/09/08**
Update count: **0**

Registration date

2018-11-29, 1397/09/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

2017-04-22, 1396/02/02

Actual recruitment end date
2017-07-26, 1396/05/04
Trial completion date
2017-12-01, 1396/09/10

Scientific title
Treatment of interstitial cystitis; clinical effectiveness of hydrodistention with intravesical hyaluronic acid (cystistat®) over hydrodistention alone

Public title
Effectiveness of hyaluronic acid for the treatment of interstitial cystitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Older than 18 years' old Previously treated with a daily 25 mg of Amitriptyline for at least 1 month, and did not show any improvement in symptoms.
Exclusion criteria:
History of bacterial cystitis in the last 3 months History of active genital herpes History of vaginal cervical or uterine cancer History of diverticulum History of cyclophosphamide consumption History of bladder tuberculosis History of abdomen or pelvis radiotherapy Vaginitis symptoms History of bladder stones History of symptom relief with antimicrobials or anticholinergics Frequency of urination less than 8 times a day History of benign or malignant bladder tumors
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization was used.patients were assigned to intervention and control groups using random assignment list generated by PASS software.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the patients and the doctor were aware of the allocated treatment, so blinding was not possible. but the researcher who evaluated the questionnaires and the statistical analyst of the study were completely unaware about the treatment of each patient.
Placebo
Not 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
Faculty of Medicine, University Campus, Azadi Square
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Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2016-12-21, 1395/10/01
Ethics committee reference number
IR.MUMS.fm.REC.1395.456

Health conditions studied

1

Description of health condition studied
Interstitial cystitis / bladder pain syndrome
ICD-10 code
N30.1
ICD-10 code description
Interstitial cystitis (chronic)

Primary outcomes

1

Description
Frequency of urination
Timepoint
Baseline, 1 week, 1 month, and 3 months after intervention
Method of measurement
the O`Leary-Sant questionnaire

2

Description
urgency
Timepoint
Baseline, 1 week, 1 month, and 3 months after intervention
Method of measurement
the O`Leary-Sant questionnaire

3

Description
nocturia
Timepoint
Baseline, 1 week, 1 month, and 3 months after intervention
Method of measurement
the O`Leary-Sant questionnaire

4

Description
dysuria
Timepoint
Baseline, 1 week, 1 month, and 3 months after intervention
Method of measurement
the O`Leary-Sant questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients were provided with instructions needed before hydrodistention and told not to use a diet that exacerbates interstitial cystitis symptoms. If urinary tract infection was diagnosed, the patient was treated with antibiotics for a week. Hydrodistention was performed under general anesthesia. at first, a urologist performed cystoscopy. The bladder was dilated with normal sterile saline for 1-2 minutes. Then the bladder was emptied and refilled to allow the urologist to see the lesions and wounds perfectly. Therapeutic Hydrodistention was continued for another 8 minutes. In the 12 patients of the intervention group, Cystistat® solution (40mg of sodium hyaluronate in a 50ml vial) produced by Mylan company was infused into the bladder through a catheter. patients had to keep the solution in their bladder for at least 30 minutes and place in different positions, then drained it by urinating. This procedure was done weekly for four weeks, then monthly until two months later.
Category
Treatment - Drugs

2

Description
Control group: The 12 patients of the control group were provided with instructions needed before hydrodistention and told not to use a diet that exacerbates interstitial cystitis symptoms. If urinary tract infection was diagnosed, the patient was treated with antibiotics for a week. Hydrodistention was performed under general anesthesia. at first, a urologist performed cystoscopy. The bladder was dilated with normal sterile saline for 1-2 minutes. Then the bladder was emptied and refilled to allow the urologist to see the lesions and wounds perfectly. Therapeutic Hydrodistention was continued for another 8 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urology Clinic of Imam Reza Hospital
Full name of responsible person
Mohammadreza Darabi Mahboub
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Sponsors / Funding sources

1

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Dr Mohsen Tafaghodi
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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
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
Mashhad University of Medical Sciences
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Position
Associate professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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