ISRCTN25030604 https://doi.org/10.1186/ISRCTN25030604

Application study of pressure- and volume-controllable balloon in direct visualisation interstitial cystitis dilation surgery

Submission date
04/07/2025

Recruitment status
No longer recruiting

Registration date
21/07/2025

Overall study status
Completed

Last Edited
18/08/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Interstitial cystitis/bladder pain syndrome (IC/BPS) is a long-term condition causing bladder pain, frequent urination, and urgency, which significantly reduces patients' quality of life. While treatments like bladder hydrodistension (stretching the bladder with fluid) are used, they can sometimes cause serious complications (e.g., bladder rupture). This study aims to test a new method (pressure- and volume-controlled balloon dilation) to see if it is safer and more effective than traditional hydrodistension for treating IC/BPS.

Who can participate?
Women aged 52–77 years diagnosed with IC/BPS

What does the study involve?
Participants were randomly assigned to one of two groups:
Experimental group: Underwent pressure- and volume-controlled balloon dilation (a balloon catheter inserted into the bladder to slowly inflate it with saline while monitoring pressure /volume).
Control group: Received traditional bladder hydrodistension (bladder stretched with fluid at a fixed pressure for 2 minutes under anaesthesia).
Both groups completed questionnaires about symptoms (e.g., pain, urination frequency) and bladder function tests before treatment and at follow-ups (2 weeks, 1/2/3/6 months after treatment).

What are the possible benefits and risks of participating?
Participants may experience reduced bladder pain and improved urination symptoms. The new method might lower risks like bladder rupture compared to traditional treatment.
Both procedures carried risks (e.g., temporary discomfort, bleeding). The new method aimed to reduce severe complications (e.g., bladder rupture), but unexpected side effects could occur.

Where is the study run from?
Dalian Friendship Hospital (China)

When is the study starting and how long is it expected to run for?
May 2013 to December 2023

Who is funding the study?
Dalian Friendship Hospital (China)

Who is the main contact?
Jinyi Yang, hfty999@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Jinyi Yang

Contact details
Building 1
Sanba Square
Friendship Hospital
Zhongshan District
Dalian
China
116007
+86 (0)13500723870
hfty999@126.com

Additional identifiers

Study information

Scientific Title
Pressure- and volume-controllable balloon in interstitial cystitis

Study objectives
To evaluate the efficacy and safety of pressure- and volume-controlled balloon dilation in the treatment of interstitial cystitis/bladder pain syndrome (IC/BPS) and to compare it with traditional bladder hydrodistension

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/12/2024, Dalian Friendship Hospital (Building 1, Sanba Square, Friendship Hospital, Zhongshan District, Dalian, 116007, China; +86 (0)411 82718822; yangjinyi_y047@163.com), ref: LL-2024-052-01

Primary study design

Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Interstitial cystitis/bladder pain syndrome (IC/BPS)

Interventions
Women with IC/BPS were randomly assigned to a pressure- and volume-controlled balloon dilation group (experimental group, n = 25) or a traditional bladder hydrodistension group (control group, n = 25).

Randomization:
Participants will be randomly assigned (1:1 ratio) to either group using computer-generated sequences, with odd-numbered participants allocated to hydrodistension and even-numbered participants to balloon dilation.

Blinding:
No blinding will be applied to participants or operators due to the nature of the interventions, but outcome assessors will be blinded to group allocation.

Conventional bladder hydrodistention:
Preoperative preparation: Patient assessment, including medical history, physical examination and necessary laboratory tests, was carried out to confirm the patient's suitability for surgery. A fasting period of 6–8 hours prior to surgery was observed to minimise anaesthesia-related risks. Procedure: Under anaesthesia, bladder perfusion was performed at a set pressure of 80 cmH_2O for 2 minutes, and bladder capacity was recorded. A cystoscope was used to visualise the bladder wall and detect any ulcers or abnormalities. Saline solution was gradually instilled using a three-chamber balloon catheter to progressively expand bladder capacity, ensuring no abnormalities during instillation. Dilatation was maintained for 8 minutes before the bladder fluid was slowly drained to prevent complications upon cystoscope withdrawal. Postoperative treatment: In the absence of active bleeding, infusion therapy (sodium heparin + sodium carbonate + lidocaine + sodium chloride) was administered directly into the bladder. Patients were then transferred to the recovery room and monitored until they had fully recovered from anaesthesia.

Pressure- and volume-controlled balloon dilatation:
Preoperative preparation: Patient assessment was performed to confirm the absence of contraindications, and a fasting period of 6–8 hours prior to surgery was observed. Procedure: A urethral insertion of an expander with a pressure- and volume-controlled balloon was carried out and connected to a control device. Sterile saline solution was gradually infused while real-time monitoring of bladder volume and pressure was conducted. Cystoscopy was used to observe the bladder wall and confirm the absence of complications during dilatation. Dilatation was maintained for 8 minutes, followed by slow evacuation of fluid with continued observation for abnormalities. Postoperative management: Patients without active bleeding received intravesical drug instillation as part of the postoperative treatment. Postoperative follow-up evaluations were conducted to assess recovery.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Balloon catheter

Primary outcome(s)
1. Pelvic pain and urinary frequency measured using the O'Leary-Sant Interstitial Cystitis Symptom and Problem Index questionnaire at baseline, 2 weeks, 1 month, 2 months, 3 months, and 6 months post-treatment.
2. Pelvic pain and urinary frequency measured using the pelvic pain and urinary frequency (PUF) questionnaire at baseline, 2 weeks, 1 month, 2 months, 3 months, and 6 months post-treatment

Key secondary outcome(s)
1. Maximum voided volume (MVV) measured using a 24-hour bladder diary at baseline, 2 weeks, 1 month, 2 months, 3 months, and 6 months post-treatment
2. Bladder capacity ratio (pre-/post-dilation) measured using cystoscopic volume assessment at 6 months post-treatment
3. Nocturia episodes measured using patient-reported sleep logs at baseline, 2 weeks, 1 month, 2 months, 3 months, and 6 months post-treatment
4. Postoperative complications (bleeding, bladder rupture) recorded via clinical documentation at 2 weeks and 6 months post-treatment
5. Treatment satisfaction measured using a 5-point Likert scale questionnaire (developed by the study team) at 6 months post-treatment

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. The diagnosis of IC was based on internationally recognised diagnostic criteria
2. The age range of participants was 18 to 80 years
3. Participants were required to have the ability to comprehend and adhere to study requirements, including completion of all necessary assessments and tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Female

Total final enrolment
50

Key exclusion criteria
1. Severe heart, liver or kidney disease
2. Currently undergoing treatment or taking medication that might interfere with the study results
3. Mental illness or cognitive impairment that could affect their understanding of the research
4. Pregnant or lactating women
5. Previously undergone bladder dilatation or related surgeries
6. A history of allergies to drugs or materials used in the procedure
7. Active autoimmune diseases or other conditions affecting the immune system
8. Recent use of anticoagulants within the past 3 months constituted an exclusion criterion
9. Experiencing severe psychosocial problems, such as major depression or suicidal tendencies

Date of first enrolment
01/07/2013

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
China

Study participating centre
Friendship Hospital
Building 1, Sanba Square, Zhongshan District
Dalian, Liaoning
China
116007

Sponsor information

Organisation
Dalian Friendship Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/08/2025	18/08/2025	Yes	No