

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Protokin therapy in the management of painful bladder syndrome/interstitial cystitis: A pilot study

Protocol summary

Study aim

Determining the effect of protokine therapy in the treatment of painful bladder syndrome/interstitial cystitis

Design

In the current pilot study, 10 patients diagnosed with BPS/IC in Imam Reza Hospital, Tabriz, who did not respond to medical treatment, will be included in the study.

Settings and conduct

The study will be conducted as a pilot study on 10 volunteer patients suffering from painful bladder syndrome/interstitial cystitis, and there will be no randomization and blinding, and the before and after values will be compared.

Participants/Inclusion and exclusion criteria

All patients with painful bladder syndrome/interstitial cystitis who are resistant to first, second, and third-line treatment (Botox injection). Patients who have the Bladder Pain/Interstitial Cystitis Symptom Score (BPIC-SS) questionnaire completed by the specialist in the file. Patients who have urodynamic evaluation before injection.

Intervention groups

10 patients diagnosed with BPS/IC who did not respond to medical treatment, will be included in the study. On the morning of the injection, 10 cc of blood is taken from the person (using a protokine syringe) and incubated at 37 degrees Celsius for 6-9 hours and centrifuged at 5000 rpm for 6 minutes. Finally, 4.5 to 5 cc of plasma is obtained, which is separated from the syringe using a 0.02 serum filter and ready for use. The patient undergoes general or local anesthesia for protokine injection. Cystoscopy is performed using a 19f rigid cystoscope in the lithotomy position. After the bladder is filled with 150 ml of liquid, 5 cc of Protokine is injected into 10 to 20 areas in the bladder wall of each patient. The injection is performed using a 27-gauge disposable needle. The injection is done in the entire wall of the bladder.

Main outcome variables

Response rate to treatment based on BPIC-SS questionnaire scores in patients before and after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130306012728N9**

Registration date: **2023-11-05, 1402/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-05, 1402/08/14**

Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

Name

Sakineh Hajebrahim

Name of organization / entity

Urology Department, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7328

Email address

ebrahimis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-03, 1402/06/12

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Protokin therapy in the management of painful bladder syndrome/interstitial cystitis: A pilot study

Public title
Protokin therapy in the management of painful bladder syndrome/interstitial cystitis: A pilot study

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients with painful bladder syndrome/interstitial cystitis who were resistant to first, second and third line treatment (Botox injection). Patients who had urodynamic evaluation before injection
Exclusion criteria:
 Lack of consent to participate in the study

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Tabriz University of Medical Sciences
Street address
 Research Center for Evidence-based Medicine, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran, Azadi Street- Golgasht Ave,

Tabriz, East Azarbaijan, Iran.
City
 Tabriz
Province
 East Azarbaijan
Postal code
 5166/15731
Approval date
 2023-06-12, 1402/03/22
Ethics committee reference number
 IR.TBZMED.REC.1402.223

Health conditions studied

1

Description of health condition studied
 Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)
ICD-10 code
 N30.1
ICD-10 code description
 Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

Primary outcomes

1

Description
 BPIC-SS questionnaire scores
Timepoint
 Before and 1 and 3 months after injection
Method of measurement
 BPIC-SS questionnaire

2

Description
 Determining the level of patients' satisfaction with the intervention
Timepoint
 Before and 1 and 3 months after injection
Method of measurement
 Based on the evaluation checklist, the patient's satisfaction with the procedure is measured from completely satisfied to completely dissatisfied: the evaluated questions include: completely satisfied, somewhat satisfied, dissatisfied, completely dissatisfied

3

Description
 Determining the amount of side effects in patients
Timepoint
 1 and 3 months after injection
Method of measurement
 Checklist for any side effects

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Protokine therapy. 10 cc of blood is taken from the patient (using a protokine syringe) and incubated at 37 oc for 6-9 hours and centrifuged at 5000 rpm for 6 minutes. Finally, 4.5 to 5 cc of plasma is obtained, which is separated from the syringe using a 0.02 serum filter and ready for use. In order to inject protokine, the patient will be under general or local anesthesia. Cystoscopy is performed using a 19f rigid cystoscope in the lithotomy position. After the bladder is filled with 150 ml of fluid, 5 cc of Protokine is injected into 10 to 20 areas in the bladder wall of each patient. The injection is performed using a 27-gauge disposable needle. The injection is done in the entire wall of the bladder.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Sakineh Hajebrahimi

Street address

Research Center for Evidence-based Medicine,
Faculty of Medicine, Tabriz University of Medical
Sciences, Tabriz, Iran, Azadi Street- Golgasht Ave,
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Email

ebrahimis@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahbi

Street address

دانشگاه علوم پزشکی تبریز

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Phone

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh hajebrahimi

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Research Center for Evidence-based Medicine,
Faculty of Medicine, Tabriz University of Medical
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sakineh Hajebrahimi

Position

Professor

Latest degree

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Other areas of specialty/work

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Data on the main outcome will be published

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

It will be available only to researchers working in
academic and scientific institutions

Under which criteria data/document could be used

In order to help scientific progress in the field of research

From where data/document is obtainable

Sakineh Hajebrahimi ebrahimis@tbzmed.ac.ir

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

Scientific approval of the applicant by Tabriz University
of Medical Sciences

Comments