

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Assessment of the effect of transurethral intraprostatic injection of botulinum toxin type A on males with chronic pelvic pain syndrome & refractory to conventional therapy referred to Razi hospital

#### Protocol summary

##### Summary

Chronic pelvic pain syndrome (CPPS) has substituted the previously used classification of nonbacterial prostatitis & prostatodynia. Although medical approaches have reduced CPPS symptoms, thus the objective of the current a pilot double blind & randomized placebo-controlled clinical trial study is to evaluate the safety & efficacy of transurethral intraprostatic injection of BoNT-A for the treatment of men diagnosed with CPPS refractory to conventional medical therapies. 60 Men referred to Razi Hospital with a clinical diagnosis of CPPS and refractory to 4-6 weeks conventional medical therapy will be treated with intraprostatic BoNT-A or placebo(NI.Saline) & followed for 1 week (complications),1 & 3 months (primary efficacy analyses),6months (long term follow-up) for responders. Patients undergo baseline evaluation including history, clinical examination, NIH-CPSI, IPSS ,VAS score & QoL score questionairs , sonography, 4-Glass test & Uroflowmetry.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208051853N8**

Registration date: **2012-09-08, 1391/06/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-08, 1391/06/18

##### Registrant information

##### Name

Siavash Falahatkar

##### Name of organization / entity

Urology Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3352 5259

##### Email address

urc@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Urology Research Center, Guilan University of Medical Sciences

##### Expected recruitment start date

2012-06-04, 1391/03/15

##### Expected recruitment end date

2013-09-06, 1392/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of the effect of transurethral intraprostatic injection of botulinum toxin type A on males with chronic pelvic pain syndrome & refractory to conventional therapy referred to Razi hospital

##### Public title

Effect of transurethral intraprostatic injection of botulinum toxin type A on chronic pelvic pain syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age>18; clinical diagnosis of CPPS defined as symptoms of discomfort or pain in the

perineal or pelvic region for at least the past 3 months without evidence of bacterial infection; aggregate score of greater than or equal to 10 on the NIH-CPSI questionnaire; failed empirical therapy for 4-6 weeks  
Exclusion criteria: history of prostate; bladder or urethra cancer; pelvic radiation or systemic chemotherapy or intravesical chemotherapy; neurological disease affecting the bladder; previous intraprostatic injection of BoNT-A; PVR>200 cc; history of prostate surgery; urinary catheter; cystostomy or nephrostomy; penile or urinary sphincter implants; PSA > age- specific range; coagulopathies; during the last month: intake of antibiotics,alpha-receptor blockers,anticholinergics; intake of analgesics containing opioids; during the last 3 months:documented urinary infection,epididymitis,positive urinary cultures,STD; during the last 6 months:5-alpha reductase inhibitor; during the last 12 months: genital herpes, not adjustable HTN; angina pectoris; heart failure; status post MI; coronary bypass surgery or coronary dilatation; during the last 24 months: cerebral insult; serum creatinin >2 mg/dl; hypersensitivity concerning any substances of content of BoNT-A or myasthenia gravis; abuse of drugs or alcohol during last 5 years

**Age**

From **18 years** old to **149 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Guilan University of Medical Sciences

**Street address**

Namjoo Street

**City**

Rasht

**Postal code****Approval date**

2012-05-23, 1391/03/03

**Ethics committee reference number**

1910095609

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

chronic pelvic pain syndrome

**ICD-10 code**

N41.8

**ICD-10 code description**

Other inflammatory diseases of prostate

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

Chronic pelvic pain syndrome

**Timepoint**

before injection, 1,3,6 months after injection

**Method of measurement**

NIH-CPSI questionnaire

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

IPSS total score

**Timepoint**

before injection, 1,3,6 months after injection

**Method of measurement**

IPSS questionnaire

**2****Description**

patient's pain scaling

**Timepoint**

before injection, 1,3,6 months after injection

**Method of measurement**

Visual Analog Scale score questionnaire

**3****Description**

patient's quality of life scoring

**Timepoint**

before injection, 1,3,6 months after injection

**Method of measurement**

QoL score questionnaire

**4****Description**

Max flow rate

**Timepoint**

before injection, 1,3,6 months after injection

**Method of measurement**

Uroflowmeter

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

transurethral intraprostatic injection of 20 U/ML

Botulinum Toxin type-A

**Category**

Treatment - Drugs

**2****Description**

transurethral intraprostatic injection of 0.9% normal saline

**Category**

Placebo

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

Razi Hospital

**Full name of responsible person**

Dr. Elahe Shahab (Rezident)

**Street address**

Urology Research Center, Razi Hospital

**City**

Rasht

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

Urology Research Center

**Full name of responsible person**

Dr. Siavash Falahatkar

**Street address**

Razi Hospital, Urology Research Center

**City**

Rasht

**Grant name**

10506

**Grant code / Reference number**

32

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Urology Research Center

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Urology Research Center

**Full name of responsible person**

Dr. Elahe Shahab

**Position**

Co worker/Resident

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Urology Research Center

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Dr. Siavash Falahatkar

**Position**

Proffesor of Guilan University of Medical Sciences

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Urology Research Center

**Full name of responsible person**

Samaneh Esmaeili

**Position**

Bachelor/ Accountant of Urology Research Center

**Other areas of specialty/work**

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**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*