

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

Other areas of specialty/work**Street address**

Urology Research Center, Razi Hospital

City

Rasht

Postal code**Phone**

+98 13 1552 5259

Fax**Email**

Shah3000us@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urology Research Center

Full name of responsible person

Dr. Siavash Falahatkar

Position

Proffesor of Guilan University of Medical Sciences

Other areas of specialty/work**Street address**

Urology Research Center, Razi Hospital

City

Rasht

Postal code

41448-95655

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

urc@gums.ac.ir

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

Urology Research Center

Full name of responsible person

Samaneh Esmaeili

Position

Bachelor/ Accountant of Urology Research Center

Other areas of specialty/work

Street address

Urology Research Center, Razi Hospital

City

Rasht

Postal code

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

urc@gums.ac.ir; samaneh_815@yahoo.com

Web page address

www.urology.ac.ir

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