

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The efficacy of botox in treating peyronie disease; a clinical trial

Protocol summary

Summary

Peyronie's Disease more recently Chronic Inflammation of the Tunica Albuginea , is a connective tissue disorder involving the growth of fibrous plaques in the soft tissue of the penis, scar tissue forms in the tunica albuginea, the thick sheath of tissue surrounding the corpora cavernosa causing pain, abnormal curvature, erectile dysfunction, indentation, loss of girth and shortening. A variety of treatments have been used, but none have been especially effective Purpose: Test of Botox in treatment of peyronie Method : 10 peyronie patients analyzed by sonography to determine the size of plaque, curve of penis and sex intercourse satisfaction . then 100 unites of Botox is dissolved in 5ml normal saline, and injected in outside plaque and follow up the patient in 8 & 16 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203129274N1**

Registration date: **2012-05-30, 1391/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Mehdi Yazdinejad

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1416 4950

Email address

yazdi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2011-07-27, 1390/05/05

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of botox in treating peyronie disease; a clinical trial

Public title

The efficacy of botox in treating peyronie disease; a clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: stable peyronie plaque. Exclusion criteria : active phase of peyronie disease; less than 1 year history of peyronie disease and allergy to botox

Age

No age limit

Gender

Male

Phase

N/A

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
ahvaz jondishpour univcity of medical science
Street address
ahvaz jondishpour univcity of medical science,
golestan, ahvaz
City
ahvaz
Postal code
6125733118
Approval date
2011-06-26, 1390/04/05
Ethics committee reference number
eth235

Health conditions studied

1

Description of health condition studied
peyronie disease
ICD-10 code
N48.6
ICD-10 code description
induratio penis plastica

Primary outcomes

1

Description
size of plaque
Timepoint
preinjection and postinjection(8,16 weeks later)
Method of measurement
with sonography , milimeter

2

Description
penile curvature
Timepoint
preinjection and postinjection(8,16 weeks later)

Method of measurement
with photography , degree

3

Description
imprvement of sexual intercourse
Timepoint
preinjection and postinjection(8,16 weeks later)
Method of measurement
clinical

Secondary outcomes

1

Description
side effect
Timepoint
preinjection and post injection (8 ,16 weeks later)
Method of measurement
clinical

Intervention groups

1

Description
patients were treated with 100 unith of botox in 5cc of
normal saline (intralesional)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Dr Mehdi Yazdinejad
Street address
Golestan hospital, Golestan
City
Ahvaz

2

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Dr Mehdi Yazdinejad
Street address
Azadegan street
City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Ahvaz University of Medical
Science and Health science

Full name of responsible person

Dr. Mostafa Feghi

Street address

Golestan

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Research Deputy of Ahvaz University of Medical Science
and Health science

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**

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Mehdi Yazdinejad

Position

MD

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Mohammad Ali Hosseini

Position

Associate Professor

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

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Web page address

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