Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of therapeutic efficacy of physiotherapy and botulinum toxin injection in treatment of vaginismus and comparison of sexual function of them

Protocol summary

Summary

Aims:Evaluation of therapeutic efficacy of physiotherapy and botulinum toxin injection in treatment of vaginismus and comparison of sexual function of them in vaginismus patients referred to women sexual health and women clinics of Imam Khomeini hospital Backgrounds : The Diagnostic and Statistical Manual of Mental Disorders (DSM IV) defines vaginismus as occurring when there is recurrent or persistent involuntary spasm of the musculature of the outer third of the vagina that interferes with coitus and causes marked distress or interpersonal difficulty. clinical prevalence vary from5% to 17%. It could lead to marital disharmony, guilt feeling, anxiety and low self confidence. The aim of this study was to assess the therapeutic efficacy of physiotherapy and botulinum toxin injection in treatment of vaginismus and comparison of sexual function of them in vaginismus patients. Methods: this study is a clinical trial .74 patients from sexual health and women clinics of Imam Khomeini hospital were enrolled in the study.Inclusion criteria is 20-40 years old nonpregnant women of sexual health and women clinics of Emam Khomeini hospital which have grade 3 or 4 vaginismus on lamont grading; they dont have any botulinum toxin containdication(albumin and botulinum or injectable component alergy; infection of injection site; pregnancy; nerve and muscle desease such as Myasthenia Gravis and Lambert Eaton syndrome; coagulation disorders; anticoagulant drugs.Exclusion criteria is pregnant women; pregnancy planing; botulinum contraindication; poor cooperation; secondary vaginismus; Vvlvdynya; skin .patient were divided randomly into two groups(35 cases & 35 control) : physiotherapy and dysport. on the method of dysport 150-400 U disport was equally injected in the puborectalis muscles ,3 points on each side .on the method of physiotherapy patients undergoing pelvic floor anatomy training ,massage the muscle of the pelvic floor ,biofeedback and sensation focus during weekly session till 10session.a week of completed treatment ,we check libido,arousal,lubrication,orgasm,sexual satisfaction,pain. questionaries were completed by patients and results in SPSS software and with statistical using tests were analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061828486N1**
Registration date: **2017-03-12, 1395/12/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Mansooreh Yaraghi

Name of organization / entity

Tehran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date
2017-04-08, 1396/01/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of therapeutic efficacy of physiotherapy and botulinum toxin injection in treatment of vaginismus and comparison of sexual function of them

Public title
Effect of physiotherapy and botulinum toxin injection in treatment of vaginismus
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria:20-40 years old nonpregnant women of sexual health and women clinics of emem khomeini hospital which have grade 3 or 4 vaginismus on lamont grading; they dont have any botulinum toxin containdication(albumin and botulinum or injectable component alergy; infection of injection site; pregnancy; nerve and muscle desease such as Myasthenia Gravis and Lambert Eaton syndrome; coagulation disorders; anticoagulant drugs exclusion criteria:pregnant women; pregnancy planing; botulinum contraindication; poor cooperation; secondary vaginismus; Vvlvdynya; skin disorders of vulve or Perineum; anal fissure; urinary or deficatory disorders; infection of injection site; previous botulinum treatment; previous physiotherapy
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Table of random numbers

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran medical University
City
Tehran
Postal code
Approval date
2017-02-07, 1395/11/19
Ethics committee reference number
IR.TUMS.IKHC.REC.1395.1665

Health conditions studied

1

Description of health condition studied
Psychogenic vaginismus
ICD-10 code
F52.5
ICD-10 code description
Spasm of the pelvic floor muscles that surround the vagina, causing occlusion of the vaginal opening. Penile entry is either impossible or painful

Primary outcomes

1

Description
Libido
Timepoint
before and 1week after Treatment
Method of measurement
Demographic questionaries and women sexual function questionaries(FSFI)

2

Description
arousal
Timepoint
before and 1 week after Treatment
Method of measurement
Demographic questionaries and women sexual function questionaries(FSFI)

3

Description

lubrication

Timepoint

before and 1 week after Treatment

Method of measurement

Demographic questionaries and women sexual function questionaries(FSFI)

4

Description

orgasm

Timepoint

before and 1 week after Treatment

Method of measurement

Demographic questionaries and women sexual function questionaries(FSFI)

5

Description

Sexual Satisfaction

Timepoint

before and 1 week after Treatment

Method of measurement

Demographic questionaries and women sexual function questionaries(FSFI)

6

Description

pain

Timepoint

before and 1 week after Treatment

Method of measurement

Demographic questionaries and women sexual function questionaries(FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1:injection of botulinum toxin (dysport):500 unit is diluted in 1.5 cc N/S.150-400 U disport was equally injected in the puborectalis muscles ,3 points on each side with 23 needle.in severe desease before injection 1_5 mg midazolam and 50-150 mg phentanyle are used for sedation.during treatment oxygen and pulse oximetry is done.the initial dose is 150-200 u and may gradually increase till 400 unit to prevent side effect.after injection the paitent is discharged.

Category

Treatment - Drugs

2

Description

Control group:Physiotherapy: relaxation exercises, biofeedback, desensitization and focus sensory (sensation focus) is used during weekly meetings.Patients initially trained in pelvic floor anatomy . At each visit, pelvic floor muscle massage is done in lithotomy position under infrared light to increase blood flow by therapist and exercises to relax the pelvic floor muscles and breathing exercises will be taught to do at home.Then, when the patient is admitted vaginal examination,The therapist began to gradually vaginal penetration with a finger and When patients tolerate a finger۹ vaginal tampon used for 5 hours to cause further relaxation.This practice will be repeated up to three times per dey at home.At this time, in addition to tampons , vaginal electrodes tense and frequency waves used for analgesic.Sensation focus technique done by the partner at home,Where massage the entire body except breast and genital areas without penetration causes the patient feel peace. Therapy sessions along with home exercise therapy in patients continue to recover. Average of meeting are 10 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital,Sexual Health Clinic and Gynecologic Clinic

Full name of responsible person

Mansooreh Yaraghi dr

Street address

Emam Khomeini Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

-

Street address

Keshavarz street,Ghods street,central Organization of Tehran University of Medical Sciences,6 floor

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

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
Tehran University Of Medical sciences
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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