

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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 from 5% 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 Imam Khomeini hospital which have grade 3 or 4 vaginismus on lamont grading; they don't have any botulinum toxin contraindication (albumin and botulinum or injectable component allergy; infection of injection site; pregnancy; nerve and muscle disease such as Myasthenia Gravis and Lambert Eaton syndrome; coagulation disorders; anticoagulant drugs. Exclusion criteria is pregnant women; pregnancy planning; botulinum contraindication; poor cooperation; secondary vaginismus; Vvldynya; skin .patient were divided randomly into two groups (35 cases & 35 control) : physiotherapy and dysport. on the method of dysport 150-400 U dysport 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 10 session. a week of completed treatment ,we check libido, arousal, lubrication, orgasm, sexual satisfaction, pain. questionnaires 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

Mansoorreh Yaraghi

Name of organization / entity

Tehran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8828 0618

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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 contraindication(albumin and botulinum or injectable component allergy; infection of injection site; pregnancy; nerve and muscle disease such as Myasthenia Gravis and Lambert Eaton syndrome; coagulation disorders; anticoagulant drugs exclusion criteria:pregnant women; pregnancy planing; botulinum contraindication; poor cooperation; secondary vaginismus; Vvldynya; skin disorders of vulve or Perineum; anal fissure; urinary or defecatory disorders; infection of injection site; previous botulinum treatment; previous physiotherapy

AgeFrom **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 questionnaires and women sexual function questionnaires(FSFI)

2**Description**

arousal

Timepoint

before and 1 week after Treatment

Method of measurement

Demographic questionnaires and women sexual function questionnaires(FSFI)

3**Description**

lubrication
Timepoint
before and 1 week after Treatment
Method of measurement
Demographic questionnaires and women sexual function questionnaires(FSFI)

4

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

5

Description
Sexual Satisfaction
Timepoint
before and 1 week after Treatment
Method of measurement
Demographic questionnaires and women sexual function questionnaires(FSFI)

6

Description
pain
Timepoint
before and 1 week after Treatment
Method of measurement
Demographic questionnaires and women sexual function questionnaires(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 dysport was equally injected in the puborectalis muscles ,3 points on each side with 23 needle.in severe disease 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 patient 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 finger, vaginal tampon used for 5 hours to cause further relaxation.This practice will be repeated up to three times per day 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
Mansoorah 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

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

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Full name of responsible person

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Position

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Position

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City**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