Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of chronic pelvic pain and sexual satisfaction in women with endometriosis in two groups with and without botulinum toxin injection

Protocol summary

Study aim

An interventional study that is designed to compare chronic pelvic pain and sexual satisfaction in women with endometriosis in two groups with and without botulinum toxin injection .

Design

Phase 3 clinical trial with a control group, parallel design, using the random allocation rule is performed on 32 patients.

Settings and conduct

This randomized study will be performed on 32 patients with pelvic endometriosis and chronic pelvic pain, who refer to Yas Hospital, using a convenient sampling method. This is a double-blind study, the patient and analyzer do not know the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-50 years, chronic pelvic pain for at least 3 months, and do not start new analgesic strategies since one month before the intervention. Exclusion criteria: the existence of other causes of chronic pelvic pain, having severe untreated cervical dysplasia, History of hysterectomy and bilateral salpingo-oophorectomy, Allergy to botulinum toxin, Pregnancy or breastfeeding, History of urinary and fecal incontinence, Known pelvic prolapse, and Neuromuscular disorders.

Intervention groups

After a vaginal digital examination to identify pelvic muscles with spasms, and 20 to 30 minutes before the intervention, up to 10 mg of oral diazepam is administered and lidocaine cream 4% is applied to the determined location in the vaginal mucosa. Then, in the intervention group, a vial of 100 units of anabotulinum toxin A (Botox) is placed in 4 ccs of saline (final concentration 25 units/ml). In the control group, two to five ccs of normal saline are injected instead of Botox. The injection is performed by a gynecologist with experience in endometriosis using a sterile technique.

Main outcome variables

Chronic pelvic pain, Dysmenorrhea, Dyspareunia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N20**
Registration date: **2021-07-02, 1400/04/11**
Registration timing: **prospective**

Last update: **2021-07-02, 1400/04/11**
Update count: **0**

Registration date

2021-07-02, 1400/04/11

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3955

Email address

fdavaritanha@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of chronic pelvic pain and sexual satisfaction in women with endometriosis in two groups with and without botulinum toxin injection

Public title
The effect of Botox on chronic pelvic pain and sexual satisfaction in women with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-50 years Chronic pelvic pain for at least 3 months Do not start new analgesic strategies since one month before the intervention

Exclusion criteria:
The primary cause of chronic pelvic pain is the following: infection, gastrointestinal or psychological disorder, fibromyalgia, chronic fatigue syndrome Severe untreated cervical dysplasia History of hysterectomy and bilateral salpingo-oophorectomy Allergy to botulinum toxin Pregnancy or breastfeeding History of urinary and fecal incontinence Known pelvic prolapse Neuromuscular disorders such as myasthenia gravis or Lambert Aton syndrome

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation rule: First, 16 letters A and 16 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (botulinum toxin) or B (normal saline) are determined by a lot.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is performed double-blind, the participants and the analyzer do not know the type of treatment. Patients in the control group do not know their group therapy, with using the normal saline injection in Botox-like syringes. Also, the data analyzer does not know the codes defined for the treatment groups in the SPSS file.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran university of medical sciences

Street address
Tehran University of Medical Sciences,School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences,School of Medicine, Tehran Province, Tehran, Pour Sina St

City
Tehran

Province
Tehran

Postal code
1598718311

Approval date
2021-06-14, 1400/03/24

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.258

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80.9

ICD-10 code description
Endometriosis, unspecified

Primary outcomes

1

Description
Chronic pelvic pain

Timepoint
Twice, before the intervention and one month after the intervention

Method of measurement
Visual Analog Scale (VAS Ruler)

Secondary outcomes

1

Description
Sexual satisfaction rate

Timepoint
Once, at the end of the study

Method of measurement
Female Sexual Function Index Scoring

2

Description
Dysmenorrhea
Timepoint
Twice, before the intervention and one month after the intervention
Method of measurement
Visual Analog Scale (VAS Ruler)

3

Description
Dyspareunia
Timepoint
Twice, before the intervention and one month after the intervention
Method of measurement
Visual Analog Scale (VAS Ruler)

Intervention groups

1

Description
Intervention group: After a vaginal digital examination to identify pelvic muscles with spasms, and 20 to 30 minutes before the start of the intervention, up to 10 mg of oral diazepam is administered and lidocaine cream 4% is applied to the determined location in the vaginal mucosa. Then, a vial of 100 units of anabotulinum toxin A (Botox) is placed in 4 ccs of saline (final concentration 25 units/ml). The injection is performed by a gynecologist with experience in endometriosis using a sterile technique. When Botox is injected into one muscle, the removed needle is then inserted into the next muscle. In fact, the total dose of 100 units is divided between three to four identified areas of muscles with spasms.
Category
Treatment - Drugs

2

Description
Control group: After a vaginal digital examination to identify pelvic muscles with spasms, and 20 to 30 minutes before the start of the intervention, up to 10 mg of oral diazepam is administered and lidocaine cream 4% is applied to the determined location in the vaginal mucosa. Then, two to five ccs of normal saline are prepared. The injection is performed by a gynecologist with experience in endometriosis using a sterile technique. When normal saline is injected into one muscle, the removed needle is then inserted into the next muscle.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas hospital
Full name of responsible person
Fatemeh Davari Tanha
Street address
Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Sahraiyan
Street address
Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran
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1416634793
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

Profosor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Fatemeh Davari Tanha

Position

Profosor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Davari-Tanha, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Davari-Tanha fdavaritanha@sina.tums.ac.ir

What processes are involved for a request to access data/document

Any request for data must be sent to Dr. Davari-Tanha by email and accompanied by a written proposal confirmed by a local ethics committee.

Comments