Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of carboxytherapy in the treatment of stress urinary incontinence and sexual dysfunction

Protocol summary

Study aim
Determining and comparing the effect of carboxytherapy in the treatment of stress urinary incontinence and sexual dysfunction

Design
A randomized, Single-blinding clinical trial, with the parallel groups, Phase 3 on 60 patients

Settings and conduct
In this single-blind randomized clinical trial, 60 women eligible for inclusion in the study that refer to the clinic of Al-Zahra and Kashani hospitals in Isfahan will be included in the study and randomly divided into 2 groups. The first group will receive carbon dioxide(CO2) injection in the vaginal tissue, and the second group as the control group will not receive this treatment. Then, the score of stress urinary incontinence and the score of their sexual dysfunction in both groups will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria consist of women with stress urinary incontinence or sexual dysfunction, within the age range of 35-65 years, and at least one vaginal delivery or cesarean section. Exclusion criteria include active vaginal bleeding, vaginal infection, abnormal Pap smear, pregnancy, urinary tract infection, recent pelvic surgery, grade 2 or more pelvic organ prolapse, and treatment with antiplatelet or anticoagulant drugs.

Intervention groups
Intervention group: In this group, an injection angle of 15 degrees will inject 30 cc of carbon dioxide (CO2) in three areas of the vagina. Each person will undergo carboxytherapy twice a week for 2 months. Control group: In this group, an injection angle of 15 degrees will be inserted in three areas of the vagina, but carbon dioxide (CO2) will not be injected. It should be noted that the insertion of the needle into the vaginal tissue even without the injection of carbon dioxide (CO2) stimulates collagen production and is not harmful to the patient.

Main outcome variables
Stress urinary incontinence score; Sexual dysfunction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N27**
Registration date: **2021-04-03, 1400/01/14**
Registration timing: **prospective**

Last update: **2021-04-03, 1400/01/14**
Update count: **0**

Registration date
2021-04-03, 1400/01/14

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-20, 1400/01/31

Expected recruitment end date
2021-07-22, 1400/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of carboxytherapy in the treatment of stress urinary incontinence and sexual dysfunction

Public title
The effect of carboxytherapy in the treatment of stress urinary incontinence and sexual dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
women with stress urinary incontinence or sexual dysfunction within the age range of 35-65 years Have at least one vaginal delivery or cesarean section

Exclusion criteria:
Having active vaginal bleeding Having vaginal infection Having abnormal Pap smear Pregnancy Having urinary tract infection Recent pelvic surgery Having grade 2 or more pelvic organ prolapse Treatment with antiplatelet or anticoagulant drugs

Age
From **35 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 60 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the fact that in this study, carbon dioxide (CO2) is injected in three areas of the vagina in one group and a needle is inserted in three areas of the vagina in the other group, but no injection is performed, so the researcher will be aware of the type of intervention. But due to the similarity in performance, the patient does not know the type of intervention. Also, the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2020-12-04, 1399/09/14

Ethics committee reference number
IR.MUI.MED.REC.1399.795

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

2

Description of health condition studied
Stress urinary incontinence

ICD-10 code
N39.3

ICD-10 code description
Stress incontinence

Primary outcomes

1

Description
Urinary stress incontinence score

Timepoint
Before, one and three months after the intervention

Method of measurement
Questionnaire-Urinary Incontinence Short Form(ICIQ-UI SF)

2

Description

Sexual dysfunction score

Timepoint

Before, one and three months after the intervention

Method of measurement

Short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, a 30 gauge needle with a length of 12 mm and an injection angle of 15 degrees will inject 30 cc of carbon dioxide (CO2) in three areas of the vagina. Each person will undergo carboxytherapy twice a week for 2 months.

Category

Treatment - Other

2

Description

Control group: In this group, a 30 gauge needle with a length of 12 mm and an injection angle of 15 degrees will be inserted in three areas of the vagina, but carbon dioxide (CO2) will not be injected. It should be noted that the insertion of the needle into the vaginal tissue even without the injection of carbon dioxide (CO2) stimulates collagen production and is not harmful to the patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Zahra Allameh

Street address

Obstetrics and Gynecology Department, Kashani Hospital, Kashani Street.

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2

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Zahra Allameh

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available