

# 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(CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### 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 (CO<sub>2</sub>) 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

Isfahan

##### 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 (CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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.

###### **City**

Isfahan

###### **Province**

Isfahan

###### **Postal code**

8183983434

###### **Phone**

+98 31 3233 0091

###### **Email**

z-allameh@med.mui.ac.ir

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Al-Zahra Hospital

###### **Full name of responsible person**

Zahra Allameh

###### **Street address**

Soffe Blvd, Isfahan

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###### **Postal code**

8174675731

###### **Phone**

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###### **Email**

z-allameh@med.mui.ac.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Esfahan University of Medical Sciences

###### **Full name of responsible person**

Shaghayegh Haghjoo Javanmard

###### **Street address**

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

###### **City**

Isfahan

###### **Province**

Isfahan

###### **Postal code**

8174673461

###### **Phone**

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###### **Email**

dean@med.mui.ac.ir

##### **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

**Street address**

Department of Obstetrics and Gynecology, Al-Zahra  
Hospital, Sofeh Blvd., Tohid Street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam teimouri jervekani

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Phone**

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Maryam\_tymr@yahoo.com

## Person responsible for scientific 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

**Street address**

Department of Obstetrics and Gynecology, Al-Zahra  
Hospital, Sofeh Blvd., Tohid Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

## 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