

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### a clinical trial on the effect of biofeedback therapy in treatment of coccygodynia in patients referring to physical medicine and rehabilitation clinic of Firoozgar hospital

#### Protocol summary

##### Summary

(1) Objectives: the aim of this trial is to investigate the effect of biofeedback therapy in the treatment of patients with coccygodynia. (2) Design: it is a randomized control trial, single blinded, without placebo control, unicentral and in second or third phase of clinical trial. (3) Setting and conduct the population under research are patients with coccygodynia referring to physical medicine and rehabilitation clinic via an advertisement. the sample size is 30 people. in all patients, coccydymia is confirmed with superficial and intrarectal palpation. patients will be randomized to 2 groups of 15. (4) Participants including major eligibility criteria: inclusion criteria are age 18 to 65 years and Visual Analogue Scale equal to or more than 4 in any position of sitting, standing or supine lying and exclusion criteria are coccygeal injection or manipulation in last 2 months, history of poor control diabetes or rheumatologic diseases, coccyx dislocation and Simultaneous biofeedback therapy due to any other reason. (5) Intervention: the intervention is local injection of methylprednisolone in the point of maximum tenderness and also teaching of pelvic floor exercises for 4 weeks and lifestyle modification in one group and the same work in the other group in combination with pelvic floor biofeedback. (6) main outcome measures (variables): the patients are followed and assessed of their pain 4 and 8 weeks after the intervention with Visual Analogue Scale. also, patient's quality of life will be tested with a valid questionnaire before and after the intervention. sample collection and intervention will be done in 6 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011824621N4**

Registration date: **2016-02-17, 1394/11/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-17, 1394/11/28

##### Registrant information

###### Name

Tannaz Ahadi

###### Name of organization / entity

Iran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8871 8207

###### Email address

ahadi.t@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

a clinical trial on the effect of biofeedback therapy in treatment of coccygodynia in patients referring to physical medicine and rehabilitation clinic of Firoozgar hospital

IR.IUMS.REC.1394.26154

### Public title

the effect of biofeedback therapy in the treatment of coccygodynia

### Purpose

Treatment

### Inclusion/Exclusion criteria

inclusion criteria: age 18 to 65 years; VAS scale equal to or more than 4 in any position of sitting, standing or supine lying exclusion criteria: coccygeal injection or manipulation in last 2 months; history of poor control diabetes or rheumatologic diseases; any low back pain radiating to sacrococcygeal region or interfering with appropriate position during biofeedback therapy; history of any malignancy, coccyx dislocation; acute fissure; Simultaneous biofeedback therapy due to any other reason

### Age

From **18 years** old to **65 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Science

##### Street address

Hemmat highway, Tehran

##### City

Tehran

##### Postal code

#### Approval date

2016-01-19, 1394/10/29

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

coccygodynia

#### ICD-10 code

M53.3

#### ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified

## Primary outcomes

### 1

#### Description

coccygeal pain

#### Timepoint

before intervention, 4 and 8 weeks after intervention

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

patient's quality of life

#### Timepoint

before intervention, 4 and 8 weeks after intervention

#### Method of measurement

the standard SF36 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

in the intervention group local injection of 1cc Lidocaine and 1cc of 40 mg Methylprednisolone in the point of maximum tenderness plus teaching of pelvic floor exercises for 4 weeks and lifestyle modification plus pelvic floor biofeedback. biofeedback is a kind of physiotherapy which is done 2 sessions per week, each time for 15 minutes and in total number of 8 sessions for 1 month by a physiotherapist. Pelvic floor exercises are done 3 times a day, each time for 5 minutes by the patient.

#### Category

Treatment - Other

### 2

#### Description

in the control group local injection of 1cc Lidocaine and 1cc of 40 mg Methylprednisolone in the point of maximum tenderness plus teaching of pelvic floor exercises for 4 weeks and lifestyle modification. Pelvic

floor exercises are done 3 times a day, each time for 5 minutes by the patient.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Firoozgar educational hospital

**Full name of responsible person**

Maryam Hosseini, resident of physical medicine and rehabilitation

**Street address**

Firoozgar hospital, physical medicine and rehabilitation clinic, Behafarin street, Valiasr square, Tehran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

**Full name of responsible person**

Pejman Madani

**Street address**

Hemmat Highway, Tehran

**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, Iran 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**

Iran University of Medical Science

**Full name of responsible person**

Maryam Hosseini

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resident of physical medicine and rehabilitation

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**Full name of responsible person**

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**Position**

assistant professor of physical medicine and rehabilitation

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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*