

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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, coccydynia 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

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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

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

IR.IUMS.REC.1394.26154

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

Position

resident 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