Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Tannaz Ahadi
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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 Universiy 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 questionare

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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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