Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of pelvic floor biofeedback on pain and quality of life of patients with chronic coccydynia

Protocol summary

Study aim
To evaluate the effect of biofeedback on pain and quality of life of patients with chronic coccydynia
Design
Clinical trial with control group, with parallel groups, randomized, no blinding, on 64 patients. The rand function of Excel software was used for randomization
Settings and conduct
patients with chronic coccydynia referred to the physical medicine and rehabilitation clinic of Imam Reza Hospital in Tehran in 1403
Participants/Inclusion and exclusion criteria
Patients aged 18 to 65 years with a VAS score equal to or greater than 4 in any of the sitting, standing or lying positions for at least 2 months, with no history of coccyx injection or manipulation in the past two months, no systemic diseases (poorly controlled diabetes, rheumatoid arthritis, etc.), no history of malignancy, dislocation of the coccyx, no acute fissure, and no simultaneous biofeedback treatment to treat other pelvic floor disorders
Intervention groups
Patients with chronic pelvic pain under Kegel exercises and 8 sessions of pelvic floor biofeedback
Main outcome variables
Visual analog scale and 12-question quality of life questionnaire (SF-12)and Dallas pain questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250203064633N1**
Registration date: **2025-02-15, 1403/11/27**
Registration timing: **retrospective**

Last update: **2025-02-15, 1403/11/27**
Update count: **0**
Registration date
2025-02-15, 1403/11/27

Registrant information
Name
Hamidreza Matin
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8609 6350
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-06-21, 1403/04/01
Expected recruitment end date
2024-11-21, 1403/09/01
Actual recruitment start date
2024-07-05, 1403/04/15
Actual recruitment end date
2024-12-21, 1403/10/01
Trial completion date
2024-12-21, 1403/10/01

Scientific title
Investigating the effect of pelvic floor biofeedback on pain and quality of life of patients with chronic coccydynia

Public title
Investigating the effect of pelvic floor biofeedback on pain and quality of life of patients with chronic coccydynia
Purpose
Supportive
Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic coccyx pain with a VAS score equal to or greater than 4 in any of the sitting, standing or lying positions for at least 2 months, with no history of injection or manipulation of the coccyx in the past two months.
Exclusion criteria:
Absence of systemic diseases (poorly controlled diabetes, rheumatoid arthritis, etc.) No history of malignancy Absence of coccyx dislocation Absence of acute anal fissure Absence of simultaneous biofeedback treatment to treat other pelvic floor disorders There were patients who no longer wanted to continue the study

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Actual sample size reached: **57**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ارتش ایران kamiteh akhlagh daneshgah alum pezeshki ertash iran Ethics
Street address
West Fatemi St., not reaching Shahid Chamran Highway, Etemadzadeh St
City
تهران
Province
Tehran
Postal code
1411718546
Approval date
2024-06-11, 1403/03/22
Ethics committee reference number
IR.AJAUMS.REC.1403.058

Health conditions studied

1

Description of health condition studied
Coccydynia
ICD-10 code
M53.3
ICD-10 code description
Sacrococcygeal disorders, not elsewhere classified

Primary outcomes

1

Description
Visual Analogue Scale
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the 4th and 12th week
Method of measurement
Visual Analogue Scale

2

Description
Short form health survey 12
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the 12th week
Method of measurement
Short form health survey 12

3

Description
Dallas pain questionnaire
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the 12th week
Method of measurement
Dallas pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with coccydynia treated with Kegel exercises and 8 sessions of pelvic floor biofeedback
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital (AS) - 501 Army

Full name of responsible person
Hamidreza Matin

Street address
Tehran - Fatemi West St. - Shahid Etemadzadeh St. - Imam Reza (AS) Hospital - 501 Artesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Hamidreza Matin

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Grant name

Grant code / Reference number

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

Title of funding source
Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Hamidreza Matin

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available