

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 randomization 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)

Phone

+98 21 8609 6350

Email address

h.matin@ajautms.ac.ir

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	
<u>1</u>	
Ethics committee	
Name of ethics committee	کمیته اخلاق دانشگاه علوم پزشکی ارتش ایران 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	
<u>1</u>	
Description of health condition studied	Coccydynia
ICD-10 code	M53.3
ICD-10 code description	Sacrococcygeal disorders, not elsewhere classified
Primary outcomes	
<u>1</u>	
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
<u>2</u>	
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
<u>3</u>	
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	
<u>1</u>	
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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Web page address

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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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Tehran - Fatemi West St. - Shahid Etemadzadeh St. -
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<https://www.ajaums.ac.ir/>

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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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