

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 random 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@ajau.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**1****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**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

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

H.matin@ajaums.ac.ir

Web page address

<https://imamreza.ajaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Hamidreza Matin

Street address

Tehran - Fatemi West St. - Shahid Etemadzadeh St. -
Imam Reza (AS) Hospital - 501 Artesh1

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

H.matin@ajaums.ac.ir

Web page address

<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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

H.matin@ajaums.ac.ir

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

H.matin@ajaums.ac.ir

Person responsible for updating data

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

H.matin@ajaums.ac.ir

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