

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effects of heat controlled radiofrequency with physiotherapy on chronic pelvic pain in women

Protocol summary

Study aim

-Comparison of the effects of heat controlled radiofrequency with physiotherapy on chronic pelvic pain in women referring to Yas Hospital in 2019

Design

Controlled parallel randomized clinical trial on 60 patients

Settings and conduct

A total of 60 women with chronic pelvic pain, 30 patients in radiofrequency intervention group and 30 patients in physiotherapy intervention group, are included in this study in Yas Hospital, Tehran, Iran. The intervention is heat controlled radiofrequency or physiotherapy for treatment of chronic pelvic pain. Finally, the intensity of pain, pelvic floor muscle strength, pelvic floor muscle tonicity and muscle endurance are compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic pelvic pain. Exclusion criteria: using drugs for treatment of chronic pelvic pain.

Intervention groups

Intervention group includes women with chronic pelvic pain that are treated with heat controlled radiofrequency or physiotherapy.

Main outcome variables

Pain; Pelvic floor strength; Pelvic floor tonicity; Muscle endurance

General information

Reason for update

Error in data entry

Acronym

IRCT registration information

IRCT registration number: **IRCT20200311046746N2**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**

Update count: **1**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Nasim Shokouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4116 0852

Email address

shokouhinasim@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

2020-09-22, 1399/07/01

Actual recruitment end date

2021-03-10, 1399/12/20

Trial completion date

2021-04-19, 1400/01/30

Scientific title

Comparison of the effects of heat controlled radiofrequency with physiotherapy on chronic pelvic pain in women

Public title

Comparison of the effects of heat controlled radiofrequency with physiotherapy on chronic pelvic pain in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic pelvic pain

Exclusion criteria:

Medication for treatment of chronic pelvic pain Pelvic region malignancies Pregnancy, breastfeeding, and other related medical conditions Urinary tract infections and vaginal infections Neurological disease such as MS, CVA, and spinabifida Abnormal mental status Abnormal pap smear

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated into the case and control groups using permuted balance block randomization. The blocks are four. Using STATA software, random numbers are generated from 1 to 6. Another number is generated when the previous number is more than 6, without considering it. An individual prepare the random numbers and put them in pockets with a five-digit serial number. All pockets open after including a patient, and the patient allocates to a group.

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina Avenue

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷-۱۳۱۳۷

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.162

Health conditions studied

1

Description of health condition studied

Chronic pelvic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention, after 6 weeks and after 3 months

Method of measurement

Visual analog scale

2

Description

Pelvic floor muscle strength

Timepoint

Before the intervention, after 6 weeks and after 3 months

Method of measurement

Clinical examination

3

Description

Pelvic floor muscle tonicity

Timepoint

Before the intervention, after 6 weeks and after 3 months

Method of measurement

Clinical examination

4

Description

Muscle endurance

Timepoint

Before the intervention, after 6 weeks and after 3 months

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Radiofrequency treatment. Patients undergo a Radiofrequency twice a month for 12 weeks in Yas hospital, Tehran. Each session we are going to assess patients satisfaction using VAS.

Category

Treatment - Other

2

Description

Intervention group: Physiotherapy treatment. Patients undergo a Physiotherapy once a week for 12 weeks in Yas hospital, Tehran. Each session we are going to assess patients satisfaction using VAS.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Nasim Shokouhi

Street address

North Nejatollahi street , karim khan avenue

City

Teharn

Province

Tehran

Postal code

1597856511

Phone

+98 21 4216 0000

Email

yashospital@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Qods street, Keshavars blvd

City

Tehran

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Postal code

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Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nasim Shokouhi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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North Nejatollahi street, Karimkhan street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasim Shokouhi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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