

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Comparison of TENS current, Ultrasound and exercise with/without Tecar therapy on muscle haematoma, pain, pain pressure threshold and quality of life in Hamstring muscle strain injury

Protocol summary

Study aim

Comparison of TENS current, Ultrasound and exercise with/without Tecar therapy on muscle haematoma, pain, pain threshold and quality of life in Hamstring muscle strain injury

Design

Randomized , Single blind , Sham controlled clinical trials with parallel group design of 32 patients enrolled and follow up for 1 and 2 months

Settings and conduct

After assessment of area of hamstring muscle haematoma (bleeding), intensity of pain, pain pressure threshold and quality of life (based on SF-36 questionnaire), patients will be divided into two treatment and control groups randomly. Patients will be treated in Physiotherapy clinic of Rehabilitation faculty of Shahid Beheshti University of Medical Science.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-40, Afflicted to structural hamstring muscle strain injuries (indirect muscle injuries), Existence of muscle haematoma which is confirmed by imaging test, Patients with pain intensity of more than 3, in Visual Analog Scale, Absence of history of surgery or metal implantation in lower limb, especially in posterior area of hip and thigh, Not using Analgesic and Anticoagulant drugs, Exclusion criteria: Pregnancy, Existence of tumor or malignant tissue, Having electronic implanted device such as pace maker, Open infected wounds, Treated with radiotherapy in last 6 month, Cardiovascular disorders, Tuberculosis, Unreliable patients,

Intervention groups

Treatment group 1: patients were treated with TENS current, Ultrasound, Exercise and real Tecar therapy. Treatment group 2 (control): patients were treated with TENS current, Ultrasound, Exercise and sham Tecar therapy.

Main outcome variables

Area size of muscle haematoma, intensity of pain (based on Visual Analog Scale), intensity of pain pressure threshold and quality of life (based on SF-36 questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045187N1**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

Registration date

2019-12-27, 1398/10/06

Registrant information

Name

Seyed Ali Adabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3624 7842

Email address

aliadabi_pt@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of TENS current, Ultrasound and exercise with/without Tecar therapy on muscle haematoma, pain, pain pressure threshold and quality of life in Hamstring muscle strain injury

Public title

The effect of Tecar therapy on haematoma caused by hamstring muscle strain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-40 Structural hamstring muscle strain injuries (indirect muscle injuries) Existence of muscle haematoma which is confirmed by imaging test Patients with pain intensity of more than 3, in Visual Analog Scale Absence of history of surgery or metal implantation in lower limb, especially in posterior area of hip and thigh Not using Analgesic and Anticoagulant drugs

Exclusion criteria:

Pregnancy Existence of tumor or malignant tissue Having electronic implanted device such as pace maker Open infected wounds Treated with radiotherapy in last 6 month Cardiovascular disorders Tuberculosis Unreliable patients

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **32****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple Randomization: Patients will be assigned a number according to the order of selection and will be divided into two treatment groups by sortition. The first pulled out number would be assigned to the treatment group 1 and the subsequent numbers would be assigned treatment group 2, respectively. Stratified randomization is based on gender and Body Mass Index (BMI).

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the Participants of the Study will be blinded. Patients would be assigned in two groups randomly. Difference of two groups is in intensity of Tecar therapy(High frequency electromagnetic currents), as in control group , Sham therapy (with zero intensity) would

be applied and intensity of device in treatment group would be 20-30 percent. Patients will not be aware of intensity of Tecar device

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Science

Street address

3rd Floor, Medical Faculty, Next to the Taleghani hospital, Evin, Shahid Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.855

Health conditions studied**1****Description of health condition studied**

Muscle Strain Injury

ICD-10 code

S76.311A

ICD-10 code description

Strain of muscle, fascia and tendon of the posterior muscle group at thigh level

Primary outcomes**1****Description**

Area size of muscle haematoma

Timepoint

Before intervention, After 10 treatment sessions, After 1 and 2 month follow up

Method of measurement

Ultrasonography imaging

Secondary outcomes

1

Description

Pain intensity

Timepoint

Before intervention, After 10 treatment sessions, After 1 and 2 month follow up

Method of measurement

Based on Visual Analog Scale

2

Description

Pain Pressure Threshold

Timepoint

Before intervention, After 10 treatment sessions, After 1 and 2 month follow up

Method of measurement

By using Algometer device

3

Description

Quality of life

Timepoint

Before intervention, After 10 treatment sessions, After 1 and 2 month follow up

Method of measurement

Using SF-36 questionnaire

Intervention groups

1

Description

Intervention group: Patients in this group receive Capacitive Tecar therapy (High frequency electromagnetic currents), with intensity of 20-30 percent for 15 minutes in injury site of hamstring muscle (Posterior area of thigh), then they are treated with 25 minutes of TENS (AN analgesic electric currents with frequency of 120 Hz) , after that patients receive 3-5 minutes of Pulsed Ultrasound therapy with duty cycle of 50-80 percent . After 5 treatment sessions, Isometric and stretching hamstring muscle exercises will be added to the treatment program (treatment program includes 10 sessions in which 4 sessions would be in first week and 6 sessions in second and third week too).

Category

Rehabilitation

2

Description

Control group: Patients in this group are treated with 25 minutes of TENS (AN analgesic electric currents with frequency of 120 Hz) , after that patients receive 3-5 minutes of Pulsed Ultrasound therapy with duty cycle of 50-80 percent. Capacitive Tecar therapy (High frequency electromagnetic currents) in this group will be used as Sham therapy (with zero intensity) for 15 minutes in injury site of hamstring muscle (Posterior area of thigh). After 5 treatment sessions, Isometric and

stretching hamstring muscle exercises will be added to the treatment program (treatment program includes 10 sessions in which 4 sessions would be in first week and 6 sessions in second and third week too).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy clinic of School of Rehabilitation of Shahid Beheshti University of Medical science

Full name of responsible person

Seyed Ali Adabi

Street address

No.4, Honarmand alley , Shahid beheshti Ave, Varamin Town , Tehran

City

Varamin

Province

Tehran

Postal code

3371843433

Phone

+98 21 3624 7842

Email

aliadabi_msc@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd Floor, Medical Faculty, Next to the Taleghani hospital, Evin, Shahid Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9780

Email

zarghi@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Science

Proportion provided by this source

1

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

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

k_khademi@sbmu.ac.ir

Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Adabi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No.4, Honarmand alley , Shahid beheshti Ave,
Varamin Town , Tehran

City

Varamin

Province

Tehran

Postal code

3371843433

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+98 21 3624 7842

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Contact**Name of organization / entity**

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Postal code

3371843433

Phone

+98 21 3624 7842

Email

aliadabi_msc@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khosro Khademi-Kalantari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation of Shahid Beheshti University
of Medical Science, Damavand Ave, Emam Hossein Sq

City

Tehran

Province**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