

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effects of phonophoresis of Carum Copticum extract on pain and function in the first two weeks after anterior cruciate ligament repair.

Protocol summary

Study aim

Evaluating the effects of phonophoresis of Carum Copticum extract on pain and function of patients in the first two weeks after anterior cruciate ligament reconstruction.

Design

A Clinical trial with parallel control group, triple blind, Randomized

Settings and conduct

After assignment of patients to intervention or control groups, participants refer to physical therapy clinic of Shiraz University of Medical Sciences and receive the above mentioned treatment. The therapist is unaware of group assignment and also the assessor is unaware of group assignment and treatment and evaluate the patients at the beginning and end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years old; no injuries to the lower extremities during the past 6 months; unilateral repair of anterior cruciate ligament; the patient has undergone anterior cruciate ligament repair for the first time; lower extremity deformities. Exclusion criteria: systemic diseases like diabetes according to doctor diagnosis of specialist; patients with allergy to Carum Copticum.

Intervention groups

Intervention group: interventions of first weak includes stretching exercises, and muscle setting exercises of the muscles of lower extremities that abdominal and core strengthening exercises and ambulation are added at second weak. during two weak of treatment, electrotherapy using Russian current on quadriceps muscle to strengthen the muscle is engaged. Phonophoresis of the extract of Carum Copticum for 5-10 minutes is applied on reconstructed knee. Control group: All methods are the same as intervention group but instead of the phonophoresis of Carum Copticum extract,

routine aquagel would be used.

Main outcome variables

pain; inflammation; range of motion; weight tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160614028447N7**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **prospective**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Amin Kordi Yoosefinejad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3626 1081

Email address

yoosefinejad@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of phonophoresis of Carum Copticum extract on pain and function in the first two weeks after anterior cruciate ligament repair.

Public title
Evaluating the effects of Carum Copticum extract on pain and function of patients after anterior cruciate ligament repair.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 No injuries to the lower extremities during the past 6 months Unilateral repair of anterior cruciate ligament The patient has undergone anterior cruciate ligament repair for the first time Lower extremity malformations
Exclusion criteria:
 Systemic diseases like diabetes with a doctor's diagnosis Patients who have allergies to women

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization would be performed with block randomization method with block size of 4 using statistical software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
To blind the participants, a little amount of Carum Capticum gel with 0.5% concentration would be added to routine gel in ultrasound therapy to have similar smelling with produced gel from Carum Capticum. Also, the researcher, assessor, and analyser are blind about group assignment and activity of other members of research group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee on Ethics in Biomedical Research

Street address

Sheikh Abivardi 1, Chamran Blvd., Shiraz

City

Shiraz

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Fars

Postal code

3366971947

Approval date

2019-12-28, 1398/10/07

Ethics committee reference number

IR.SUMS.REHAB.REC.1398.044

Health conditions studied

1

Description of health condition studied

Anterior cruciate ligament repair

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes

1

Description

Pain with visual analogue scale (VAS)

Timepoint

At the beginning of study and at the end of study (after 2 weeks)

Method of measurement

With visual analogue scale which is a 10-cm straight line with zero as without pain at one end and 10 as maximum pain at the other end. The participant sign a part of line with equals his/her pain and the sign is measured with ruler and recorded as pain measure.

Secondary outcomes

1

Description

Inflammation

Timepoint

At the beginning of study and at the end (after two

weeks of interventions)

Method of measurement

Tape measurement at 15 cm below the central point of patella and 5, 10, 23 cm below the patella on both lower extremities.

2

Description

Passive and active range of motion of involved and sound knees

Timepoint

Before the beginning of study and at the end of study after 2 weeks of intervention

Method of measurement

Manual goniometry and Kinovea software

3

Description

Weight tolerance on involved knee

Timepoint

Before the beginning of study and after 2 weeks of intervention

Method of measurement

Digital scale

Intervention groups

1

Description

Intervention group: stretching of tight soft tissues, strengthening and setting exercises of knee muscles, core training, ambulation, electrotherapy using Russian current, stimulation parameters: 2500 Hz, Burst: 75, ramp up: 12 sec, 12 sec: on, 50 sec: off, Carum Copticum extract phonoresis with frequency of 1 MHz, intensity of 1.5 W/cm² for 5-10 minutes based on the volume of patients' knee

Category

Rehabilitation

2

Description

Control group: Stretching of tight soft tissues, strengthening and setting exercises, core training ambulation, electrotherapy using Russian current, stimulation parameters: frequency: 2500 Hz, Burst: 75, ramp up: 2 sec, on time: 12 sec, off time: 50 sec, Routine ultrasound therapy with frequency if 1 MHz, intensity of 1.5 W/cm², for 5-10 minutes based on the volume of patients' knee

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae hospital, Namazi hospital, Research center of Rehabilitation Sciences

Full name of responsible person

Amin Kordi Yoosefinejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yoones Ghasemi

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No. 1, Sheikh Abivardi Ave., Chamran Blvd., School of Rehabilitation Sciences

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Grant name

Vice chancellor of research of Shiraz University of Medical Sciences

Grant code / Reference number

97-01-06-18590

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Amin kordi Yoosefinejad

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Shiraz University of Medical Sciences

Full name of responsible person

Amin kordi Yoosefinejad

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data except personal information would be available.

When the data will become available and for how long

All data except personal information would be available.

To whom data/document is available

researchers of universities and scientific academies

Under which criteria data/document could be used

Researchers can use data for advanced analyses or for meta analysis studies.

From where data/document is obtainable

Dr. Amin Kordi Yoosefinejad, Shiraz, Chamran Blvd., Sheikh Abivardi 1 ave., School of Rehabilitation Sciences, Mobile: 09171950589, E-mail: yoosefinejad@sums.ac.ir

What processes are involved for a request to access data/document

After written request and precise explanation about using of data, data would be sent to researcher within a week.

Comments