

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the effect of kinesiology tape versus phonophoresis with 1% hydrocortisone on painful Hallux valgus

Protocol summary

Study aim

Evaluation of the effect of kinesiology tape versus phonophoresis with hydrocortisone 1% on painful Hallux valgus

Design

Randomized Clinical trial with parallel groups

Settings and conduct

This study is performed on 40 people in Physical medicine and rehabilitation clinics affiliated to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study; Patients with painful Hallux valgus with a mild and moderate degree of severity and without limitation in the abduction of the thumb; Exclusion criteria: Having diseases like rheumatoid arthritis, gout and mucus; A history of diabetes; History of diseases of neuropathy in lower extremity; History of dislocation or fracture in metatarsophalangeal joints; Taking high doses of corticosteroids; Taking anticoagulant drugs; Drug addiction; Having a history of previous Hallux valgus surgery or a history of lower extremity surgery that leads to imbalance; Intense Hallux valgus; Contraindication of using ultrasound.

Intervention groups

Patients are divided into two groups of 20 patients. Intervention group1: a group treated with the kinesiology tape for eight weeks (twelve times every five days) and Intervention group2: treated with phonophoresis using pulses (1 to 4) with a frequency of one megahertz and intensity w/cm²1, in the presence of hydrocortisone 1%, every 10 minutes, three times a week for one month.

Main outcome variables

Severity of pain; function; angle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N7**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **prospective**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

Registration date

2019-04-24, 1398/02/04

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-30, 1398/02/10

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of kinesiology tape versus phonophoresis with 1% hydrocortisone on painful Hallux valgus

Public title

The effect of kinesiology tape versus phonophoresis on painful Hallux valgus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Patients with painful Hallux valgus, with a mild and moderate degree of severity (the angle of Hallux valgus is 40 or less and the angle of IMA is 15 or less) and without limitation in the abduction of the thumb

Exclusion criteria:

Having diseases like rheumatoid arthritis, gout, mucus A history of diabetes History of diseases of neuropathy in lower extremity History of dislocation or fracture in metatarsophalangeal joint Taking high doses of corticosteroids Taking anticoagulant drugs Drug addiction Having a history of previous Hallux valgus surgery or a history of lower extremity surgery that leads to imbalance. Intense Hallux valgus (Hallux valgus angle is more than 40 and IMA angle is more than 15 and the limitation in thumb abduction) Contraindication of using ultrasound (acute inflammation, infection, bleeding)

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Cases are randomized using random allocation through the software. In this way, after the selection of 40 people that have the inclusion criteria, people are randomly assigned to one of the two intervention groups by statistical software.

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 Isfahan University of Medical

Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.MUI.MED.REC.1397.355

Health conditions studied

1

Description of health condition studied

Hallux valgus

ICD-10 code

M20.1

ICD-10 code description

Hallux valgus (acquired)

Primary outcomes

1

Description

Severity of pain

Timepoint

Before treatment, one week and two months after treatment

Method of measurement

VAS (Visual analogue scale)

2

Description

Function

Timepoint

Before treatment, one week and two months after treatment

Method of measurement

MOXFQ

3

Description

Angle

Timepoint

Before and a week after study

Method of measurement

Goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a group treated with the kinesiology tape for eight weeks (twelve times every five days)

Category

Treatment - Devices

2

Description

Intervention group: treated with phonophoresis using pulses (1 to 4) with a frequency of one megahertz and intensity w/cm²1, in the presence of hydroquitizon 1%, every 10 minutes, three times a week for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy and Rehabilitation Clinics of Isfahan University of Medical Sciences

Full name of responsible person

Razie Maghroori

Street address

Office of Physical Medicine and Rehabilitation, Al-Zahra Educational Center, ,Sofe St., Isfahan, Iran

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pmr@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Razie Maghroori

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Department of Physical Medicine and Rehabilitation, School of Medicine, Kashani Hospital, Isfahan University of Medical Sciences

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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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Department of Physical Medicine and Rehabilitation

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

after the investigation of researcher request and presentation of required documents will be accessible.

Comments