Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Extracorporeal shockwave therapy for chronic venous wounds: A randomized controlled trail

Protocol summary

Study aim
This study aims to assess the effect of ESWT as an adjunct therapy in chronic wound treatment.

Design
A parallel randomized clinical trial, 50 participants (25 each group), double-blind,

Settings and conduct
Fifty patients with chronic venous wounds are randomly divided into two groups of ESWT and control using random allocation software. ESWT is applied weekly along with routine compression bandaging for four weeks. The Control group receives sham ESWT along with compression bandaging. the pain score, wound size, secretion rate, patient’s satisfaction and quality of life are assessed at baseline, week 4, and week 8. The study is multi-centered and is carried out in Alzahra, Amin, and Kashani Hospitals. To blind the study, the shockwave machine is used in the control group as well, but it is off. Also, in the follow-ups, patients are assessed by a doctor who is blinded to the participants' groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: older than 18 years old, the presence of leg ulceration due to underlying venous insufficiency, ulcer size of greater than 1 cm2, ulcer must have persisted for at least 6 weeks. Exclusion criteria: the history of venous surgery in the last 6 months, known rheumatoid arthritis or systemic vasculitis, acute deep vein thrombosis, coagulopathies, tumors, diabetes, cardiovascular diseases, kidney diseases, pregnancy, having conditions unable to tolerate ESWT such as severe arterial hypertension, anticoagulant therapy, wound infection during the treatment, and resulting in antibiotic regimen, or change of treatment during the study.

Intervention groups
Intervention group: Extracorporeal shockwave therapy (ESWT) along with compression bandaging. Control group: Sham ESWT along with compression bandaging.

Main outcome variables
Wound size; secretion rate; patients’ satisfaction; quality of life; and pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190908044730N2**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **retrospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date
2020-03-29, 1399/01/10

Registrant information

Name
Mojtaba Akbari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
2018-10-23, 1397/08/01

Actual recruitment end date
2019-09-21, 1398/06/30

Trial completion date
2019-12-21, 1398/09/30

Scientific title
Extracorporeal shockwave therapy for chronic venous wounds: A randomized controlled trail

Public title
Shockwave therapy for chronic venous wounds

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: older than 18 years old. Having leg ulceration due to underlying venous insufficiency Ulcer size of greater than 1 cm2 Ulcer must have persisted for at least 6 weeks.

Exclusion criteria:
History of venous surgery in the last 6 months Known rheumatoid arthritis or systemic vasculitis, acute deep vein thrombosis, coagulopathies, tumors, diabetes, cardiovascular diseases, kidney diseases Pregnancy With conditions unable to tolerate ESWT, such as severe arterial hypertension, anticoagulant therapy Wound infection during the treatment, which would result in antibiotic regimen, or change of treatment during the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **44**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomized into intervention and control group using random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Shockwave machine is used in both the control and intervention group, but the machine is off and doesn't work in the control group. So the patients are unaware of which intervention they receive. Also, in the follow-ups, patients will be assessed by a doctor who is blinded to the participants' groups.

Placebo
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
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City
Isfehan

Province
Isfehan

Postal code
81746 73461

Approval date
2018-10-03, 1397/07/11

Ethics committee reference number
IR.MUI.MED.REC.1397.060

Health conditions studied

1

Description of health condition studied
Patients with chronic venous ulcers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Wound size

Timepoint
Week 0, 4, and 8

Method of measurement
Ruler

2

Description
Secretion rate

Timepoint
Week 0, 4, and 8

Method of measurement
Observation

3

Description
Pain intensity

Timepoint
Week 0, 4, and 8

Method of measurement

Visual Analog Scale (VAS)

4

Description
Quality of life
Timepoint
Week 0, 4, and 8
Method of measurement
Charing Cross Venous Ulcer Questionnaire (CCVUQ)

5

Description
Patients' satisfaction
Timepoint
Week 0, 4, and 8
Method of measurement
Using a scale of 0-10 (0 as completely unsatisfied and 10 as completely satisfied)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Extracorporeal Shockwave Therapy (ESWT) along with compression bandaging. Shockwave machine: electromagnetic type Dornier AR2 machine (the standard electromagnetic DUOLITH SD1, Storz Medical, Tägerwilen, Switzerland). Each ESWT session consists of 100 impulses per cm2 of the row wound area. The total energy applied for each impulse is 3.5 mJ with a frequency of 5 Hz. Patients receive one session of ESWT weekly for four weeks.
Category
Treatment - Devices

2

Description
Control group: Sham extracorporeal shock wave therapy (ESWT) along with compression bandaging. Shockwave machine: electromagnetic type Dornier AR2 machine (the standard electromagnetic DUOLITH SD1, Storz Medical, Tägerwilen, Switzerland). The machine is off, so the control group receive no shockwave. Patients receive one session of sham ESWT weekly for four weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra Hospital
Full name of responsible person
Parisa Taheri
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Soffe Boulevard, Isfahan, Iran
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Recruitment center
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Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Research Deputy

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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
Parisa Taheri

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no plan to make this available at the moment.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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