Treatment of chronic diabetic foot ulcers with Extracorporeal Shock Wave Therapy (ESWT) - a double-blind randomized controlled trial

Published: 25-09-2020
Last updated: 04-07-2024

To improve the healing rate and decrease wound surface area (WSA) of chronic diabetic foot ulcers using ESWT in combination with standard care. Furthermore, this study will investigate the long-term effects of ESWT on ulcer recurrence.

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON56830

Source
ToetsingOnline

Brief title
Shock Wave for diabetic foot ulcers

Condition

- Diabetic complications
- Epidermal and dermal conditions

Synonym
chronic diabetic foot ulcer, footwound caused by diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes mellitus, Extracorporaal Shockwave Therapie, Footulcer

Outcome measures

Primary outcome

The main study parameter is percentage of reduction in wound surface area

Secondary outcome

Secondary endpoints are time to complete healing, recurrence rate and quality

of life.

Study description

Background summary

Recently Extracorporeal Shockwave Therapy (ESWT) appeared to be an effective complementary treatment for patients with chronic diabetic foot ulcers in addition to the standard care. ESWT is a non-invasive and low-cost method for stimulating wound healing. Some promising previous studies found a higher healing rate (re-epithelization index) in the patient group that received standard care + ESWT compared to standard care only. However, these studies were limited clinical trials (low amount/small number of subjects, no placebo intervention, only single blinded), with low level of evidence.

Study objective

To improve the healing rate and decrease wound surface area (WSA) of chronic diabetic foot ulcers using ESWT in combination with standard care. Furthermore, this study will investigate the long-term effects of ESWT on ulcer recurrence.

Study design

The study will be a double-blind randomized placebo-controlled clinical trial conducted within the Erasmus Medical Center (EMC) in Rotterdam. The ESWT

treatments will be given by a physiotherapist from Fysio&Shockwave. Patients will receive 12 (placebo) ESWT treatments once a week. Follow-up will continue after the last ESWT treatment at 6, 12, and 24 weeks to evaluate the long term effects of ESWT. Total duration of the study will be 36 weeks. A pilot will be conducted to optimize the research protocol.

Intervention

The patients will receive 12 (placebo) ESWT treatments in addition to standard care. Standard care includes debridement, diabetic control, wound care, off-loading and footwear modification for pressure reduction.

Study burden and risks

In previous studies ESWT was found to be an effective and safe treatment for patients with chronic diabetic foot ulcers in addition to standard care. ESWT is a non-invasive therapy with negligible side effects, no anesthesia is needed, people can still walk and the effects are long lasting. Therefore, we believe there are minor risks in using ESWT treatments to improve the healing of diabetic chronic foot ulcers and we can consider ESWT a safe method. We only need 1 blood sample at baseline and 15 visits to the outpatient clinic will be necessary when participating in this study. As patients with an ulcer normally have to come in every 2 or 3 weeks, and we will see them twice more after the ulcer is healed, a patient with an ulcer that is closed at 12 weeks would normally attend our outpatient clinic 6 to 8 times. We ask the participants to fill out the SF-36 questionnaire 3 times. *

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age 18 years or older
• Diabetes mellitus type I or 2
• Uni- or bilateral chronic foot ulcers which have not healed for 6 weeks
• Grade 1A or 2A ulcer according to the Texas Diabetic Foot Wound Classification System
• Diameter of the ulcer > 0.5 cm and < 5 cm on the plantar side of the foot
• Ankle-brachial index > 0.7
• Toe systolic pressure > 50 mmHg
• Participants are mentally competent to understand and sign a Dutch informed consent form themselves

Exclusion criteria

• History of neoplasia or malignancy near the chronic diabetic foot ulcer
• Pregnancy
• Skeletal immaturity which has an influence on the ability to walk
• Sign of acute local infection demanding the use of systemic antibiotics or the need for amputation
• Osteomyelitis or gangrene in the affected extremity
• Severe anemia (Hb < 7,0g/dl)
• Ankle brachial index < 0.7
• Toe systolic pressure < 50 mmHg
• Any history with ESWT
• Two missed ESWT treatments
• Participation in an ongoing other clinical trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	54
Type:	Anticipated

Medical products/devices used

Generic name:	Shockwave device DUOLITH SD1 T-Top
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-09-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66337.078.20