Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Therapeutic potential of loaded doxycycline and Venlafaxine on nanofiber scaffolds for wound healing in diabetic foot

Protocol summary

Study aim
Therapeutic potential of loaded doxycycline and Venlafaxine on nanofiber scaffolds for wound healing in diabetic foot

Design
Controlled clinical trial with 20 patients,With parallel groups, Randomized

Settings and conduct
This study was performed on the treatment of diabetic foot ulcer in endocrine and Metabolism Research Center of Isfahan in a clinical trial with control group.Patients in this group were randomly selected.The intervention group received medications dressing nanofiber scaffolds and a control group without dressing nanofiber scaffolds. their wounds were tracked at intervals.

Participants/Inclusion and exclusion criteria
All individuals between the ages of 45 and 65; with a diabetic foot ulcer that has not healed despite treatment within the past month (2-7 cm); Pain at rest and during walking were included in the study and pregnant or lactating patients; Septicemia, other systemic kidney diseases such as cancer, autoimmune diseases, blood disease, liver disease, etc.; Hospitalization due to severe illness within the past two months; Severe malnutrition; foot ulcers in non-diabetic patients for example syphilis, tuberculosis, or fungal infection; Any allergy to the compounds used in the scaffolding process; patients with osteomyelitis in the foot due to diabetes; Previous wounds at the same site of study were excluded.

Intervention groups
Intervention group: Patients in this group were treated with doxycycline and venlafaxine nanofiber (NATO stayed from Nano Novin Polymer Factory) scaffolds every other day after foot wash with serum, depending on the extent of the ulcer, they were treated for one week to 20 days. Control group: Patients in this group were under normal treatment without scaffold dressing.

Main outcome variables
The size of the Ulcer, distance walked without pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160711028878N2**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

Registration date
2020-02-01, 1398/11/12

Registrant information

Name
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-10-02, 1394/07/10

Expected recruitment end date
2018-10-02, 1397/07/10

Actual recruitment start date
2015-10-07, 1394/07/15

Actual recruitment end date
2018-05-10, 1397/02/20

Trial completion date
2018-10-27, 1397/08/05

Scientific title
Therapeutic potential of loaded doxycycline and Venlafaxine on nanofiber scaffolds for wound healing in diabetic foot

Public title
Effect of a mixture of doxycycline and venlafaxine on the healing of diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 45 and 65 years Having diabetic foot ulcers that have not recovered despite a treatment during the past month (2-7 cm) Having pain at rest and walking Signature written consent

Exclusion criteria:
Pregnancy or breastfeeding septicemia Other systemic kidney diseases, such as cancer, autoimmune diseases, blood diseases, liver disease and ... Hospitalization due to severe illness in the past two months Severe malnutrition The presence of ulcers at the feet of patients, except for diabetes, for example syphilis, tuberculosis, or fungal foot Any allergy to the compounds used in the production of scaffolding Having osteomyelitis in the diabetic foot History of previous wound in the same place

Age
From **45 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
This study was a simple randomization study where 1 to 40 were written on a sheet and placed in a box in a manner that was unclear. One sheet was taken for each patient. Even numbers were assigned as the treatment group and odd numbers as the control group.

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
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, University Street, Isfahan

City
Isfahan

Province
Isfehan

Postal code
۸۱۷۴۶-۷۳۴۶۱

Approval date
2015-07-27, 1394/05/05

Ethics committee reference number
IR.MUI.REC.1395.4.079

Health conditions studied

1

Description of health condition studied
Treatment of diabetic foot ulcer

ICD-10 code
E11.5

ICD-10 code description
Type 2 diabetes mellitus with circulatory complications

Primary outcomes

1

Description
size of the Ulcer

Timepoint
Before starting the study, 2 weeks and in months of 1,2,12,18 after using drugs.

Method of measurement
biopsy

2

Description
distance walked without pain

Timepoint
Before starting the study, 2 weeks and in months of 1,2,12,18 after using drugs.

Method of measurement
Meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Nanofibers containing doxycycline

and venlafaxine were prepared from Nano Novin Polymer Factory (NATO MAND), then FTIR test was used to determine drug quantity and release rate. Their mechanical strength was then tested with a Tensile device. The morphology of the samples was analyzed by electron microscopy (TEM). The patients' foot ulcers were washed with serum and the nano-fiber scaffolds were placed on their wounds every other day, with treatment continued for one week to 20 days. Finally, the skin permeability of the drugs to nanofibers was tested on the hairless abdominal skin of the rat. The results were measured for a total duration of 12 weeks with a spectrophotometer.

Category

Treatment - Drugs

2

Description

Control group: This group had their normal treatment and scaffold dressing was not used to them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Center

Full name of responsible person

Rokhsareh Meamar

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Endocrinology and Metabolism Research Center-Khorram St.-Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Research Department of Medical Sciences

Full name of responsible person

Shaghayedgh Haghjoo Javanmard

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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

Isfahan Research Department 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

Rokhsareh Meamar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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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

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