

Treatment for diabetic foot

Submission date 07/10/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/10/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic foot disease is a serious complication of diabetes that can lead to poor blood flow in the legs and feet, making wounds difficult to heal and increasing the risk of amputation. This study looked at whether a new combination of treatments could improve outcomes for people with diabetic foot problems caused by narrowed arteries below the knee. Researchers compared two treatment approaches to see which worked better in helping wounds heal and reducing the need for further procedures or amputations.

Who can participate?

The study involved patients who were admitted to hospital with diabetic foot disease and had narrowed arteries below the knee.

What does the study involve?

Participants were divided into two groups. One group received a standard treatment using a drug-coated balloon to open up blocked arteries. The other group received a newer combination treatment that used a laser to remove blockages before using the drug-coated balloon. All participants were followed for one year to monitor their recovery and outcomes.

What are the possible benefits and risks of participating?

Patients in the study may benefit from more consistent treatment and follow-up care, which could lead to better healing and fewer complications. There were no specific risks reported for taking part in the study.

Where is the study run from?

The study was carried out in a hospital setting, starting when patients were admitted for diabetic foot treatment.

When is the study starting and how long is it expected to run for?

January 2022 to May 2024.

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Changbao Yan, 624934107@qq.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Combined interventional treatment for diabetic foot with below-the-knee arterial lesions: a prospective cohort study

Study objectives

To evaluate the clinical effect of combined interventional therapy for diabetic foot (DF) with below-the-knee (BTK) arterial lesions.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 21/12/2021, Ethics Committee of Beijing Luhe Hospital (No.82, Xinhuanan Road, Tongzhou District, Beijing, 101100, China; +86 01069543901; luheyiyuan123@163.com), ref: 2021-LHKY-064-02

Study design

Prospective interventional non randomized

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic foot with below-the-knee arterial lesions

Interventions

A prospective cohort study was conducted of 138 patients with DF complicated with BTK arterial lesions. They were assigned to two groups: the control group was treated by drug-coated balloon angioplasty, while the experimental group underwent excimer laser ablation combined with drug-coated balloon angioplasty. All patients were followed up for 1 year.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Measured using patient records at 1 year:

1. Primary patency rate
2. Target lesion revascularization rate

Key secondary outcome(s)

Measured using patient records at 1 year:

1. Primary wound healing rate
2. Secondary wound healing rate
3. Primary wound healing rate without revascularization
4. Wound healing time
5. Amputation rate
6. Mortality rate

Completion date

31/05/2024

Eligibility

Key inclusion criteria

1. DF ulcers of Wagner grades 1–4
2. Required lower extremity arterial interventional revascularization treatment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

58 years

Upper age limit

71 years

Sex

All

Total final enrolment

138

Key exclusion criteria

1. Non-ischemic diabetic foot
2. Unwilling to participate in the trial

Date of first enrolment

01/01/2022

Date of final enrolment

31/05/2023

Locations

Countries of recruitment

China

Study participating centre

Beijing Luhe hospital

No.82, Xinhuanan Road, Tongzhou District

Beijing

China

101100

Sponsor information

Organisation

Beijing Luhe Hospital Affiliated to Capital Medical University

ROR

<https://ror.org/01zyn4z03>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from (Changbao Yan /Email: 624934107@qq.com)

IPD sharing plan summary

Available on request