

# Treatment for diabetic foot

<b>Submission date</b> 07/10/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/10/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/10/2025	<b>Condition category</b> 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

Mr Changbao Yan

### ORCID ID

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### Contact details

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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 1year:

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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes