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Treatment for diabetic foot

Submission date 07/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/10/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/10/2025	**Condition category** Circulatory System	[_] Individual participant data [X] 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
https://orcid.org/0000-0001-6770-5150

Contact details
No.82, Xinhuanan Road, Tongzhou District
Beijing
China
101100
+86 1069543901
624934107@qq.com

Additional identifiers

Clinical Trials Information System (CTIS)
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 duringand/oranalysedduring the current study will be available uponrequest from (Changbao Yan /Email: 624934107@qq.com)

IPD sharing plan summary
Available on request