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Exploring how oxygen therapy and smart limb exercises can help treat diabetes-related leg artery disease

Submission date
28/11/2024

Recruitment status
No longer recruiting

Registration date
02/12/2024

Overall study status
Completed

Last Edited
02/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes mellitus (DM) is a long-term condition caused by abnormal insulin levels, leading to high blood sugar. Lower extremity arterial disease (LEAD) is a condition where arteries in the legs are blocked, causing reduced limb function or disability. People with both DM and LEAD face high risks of amputation and death, which severely impacts their quality of life and finances. Current treatments are often ineffective and expensive. This study aims to explore a new treatment combining oxygen therapy (ASOT) and limb exercises to improve blood flow and reduce symptoms, potentially lowering amputation and death rates.

Who can participate?
Adults aged 18 to 80 years who have been diagnosed with both DM and LEAD, are in stages I to IV of LEAD, are conscious, able to cooperate with treatment, and have had the disease for less than a year.

What does the study involve?
Participants will first attend a screening visit to confirm eligibility. If eligible, they will undergo assessments to measure the impact of their condition. Participants will then be divided into two groups: a control group receiving standard treatment plus exercise therapy, and a study group receiving the same treatment plus ASOT. Both groups will follow their treatment regimen once daily, 5 days a week, for 10 days. The study will compare pain levels, daily living abilities, blood glucose, cholesterol, inflammation markers, and blood flow before and after treatment.

What are the possible benefits and risks of participating?
The combined therapy of ASOT and limb exercises may reduce pain, improve self-care abilities, slow disease progression, relieve symptoms, and enhance quality of life. The therapy has few risks but should be used cautiously.

Where is the study run from?
The Second Hospital of Hebei Medical University (China)

When is the study starting and how long is it expected to run for?
November 2021 to May 2024

Who is funding the study?
The Second Hospital of Hebei Medical University (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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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
A study to explore the effect of atmospheric saturated oxygen combined with intelligent upper and lower limb rehabilitation training on diabetic lower extremity arterial disease

Study objectives

Atmospheric saturated oxygen therapy (ASOT) combined with upper and lower limb rehabilitation exercise therapy can improve the self-care ability of patients with diabetic lower limb arterial disease, delay disease progression, relieve symptoms, and improve quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/05/2024, Ethics committee of the Second Hospital of Hebei Medical University (No. 215 Heping West Road, Xinhua District, Shijiazhuang City, 050000, China; +86 311-66002789; pub@hb2h.com), ref: 2024-R255

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Lower limb rehabilitation training for patients with diabetes and lower extremity arterial disease (LEAD)

Interventions
Both groups receive standard treatment: blood glucose control (liraglutide injection, Novo Nordisk (China)), lipidlowering therapy (atorvastatin, Qilu Pharmaceutical), depressor (verapamil hydrochloride sustainedrelease capsules, Shanghai Tengry), antiplatelet therapy (aspirin, Hunan Zhongnan Pharmaceutical), anticoagulation therapy (warfarin, Qilu Pharmaceutical), circulation booster (urokinase, Guangdong Techpool BioPharma), antiinfection therapy (piperacillin /tazobactam, North China Pharmaceutical), neurotrophic support, and physical therapy. Patients with gangrene are given debridement and dressing changes to control local infection. Nursing care and education are provided in a routine fashion.
The control group receive exercise therapy in addition to the standard treatment. This involves the use of a German Motomed upper and lower limb rehabilitation trainer. Patients are seated or lying on the equipment with their backs firmly against the backrest, stabilized with a belt. For upper limb training, patients have their feet fixed on the pedals and remained stationary while their hands are fixed on the handles to perform circular movements for 30 min per session. For lower limb training, patients have their hands fixed on the handles and remained stationary while their feet are fixed on the pedals to perform circular movements for 30 min per session. When patients have difficulty performing active exercise, the responsible nurse will provide professional assistance. During the exercise, vital signs are monitored to ensure patient safety. This regimen is performed once daily, 5 days a week, for 10 days per course.
The study group receive ASOT in addition to the abovementioned regimen administered to the control group. Patients lie flat on the hospital bed with one end of a multifunctional saturated oxygen breathing apparatus connected to the ward’s oxygen supply and the other connected to an oxygen tube and mask. The mask is placed correctly over the patient’s nose and mouth and

secured with an appropriately tightened strap. Pure oxygen is inhaled using normobaric oxygen supply, with the partial pressure of oxygen set at 760 mmHg. Each session lasts 60 min, once daily, 5 days a week, for 10 days per course.

Intervention Type
Behavioural

Primary outcome(s)
1. Pain is measured using a 10 cm sliding ruler (VAS score) at baseline and after treatment
2. Barthel Index is measured using the Barthel Index rating scale at baseline and after treatment
3. Blood glucose levels are measured using a fingerstick test in the fasting state in the early morning and 2 hours after breakfast at baseline and after treatment
4. Levels of TC, TG, HDL-C, LDL-C, IL-6, CRP, and HCY are measured using a fully automated biochemical analyzer from fasting venous blood samples at baseline and after treatment
5. ABI index is measured using a Doppler stethoscope at baseline and after treatment
6. Partial pressure of oxygen within tissue microcirculation (TcPO2) is measured using a TcPO2 test at baseline and after treatment
7. DPA flow velocity on the affected side is measured using color Doppler ultrasound at baseline and after treatment

Key secondary outcome(s))
The general characteristics of the patients were measured using a questionnaire at baseline

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Meeting the diagnostic criteria for DM and LEAD
2. Confirmed to have Fontaine stage I to IV LEAD (stage I: asymptomatic; stage IIa: mild intermittent claudication; stage IIb: moderate to severe intermittent claudication; stage III: ischemic rest pain; stage IV: ischemic ulcer or gangrene)
3. Age between 18 and 80 years
4. Clear consciousness and ability to cooperate with treatment
5. Disease duration within one year
6. Provision of signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Severe cardiac, pulmonary, hepatic, or renal insufficiency
2. Recent history of fractures and chronic orthopedic diseases
3. Severe carbon dioxide retention
4. Known malignant diseases and tumor history
5. Coexisting peripheral vascular disease
6. Lack of cooperation or no provision of signed informed consent from the patient or his/her family members

Date of first enrolment
01/01/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
China

Study participating centre
The Second Hospital of Hebei Medical University
No. 215 Heping West Road, Xinhua District
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Sponsor information

Organisation
The Second Hospital of Hebei Medical University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes