Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effects of foot orthoses and exercise program in improving gait, balance and ankle muscle properties in patients after tibial pilon fracture surgery

Protocol summary

Study aim

This study aims to conduct a comprehensive assessment of the muscles, balance and gait parameters in patients who have undergone surgery for pilon fractures, before and after a physical exercise training program with or without wearing customized orthotic arch support insoles.

Design

Two arm parallel group randomised trial of 36 patients, enrolled between October 2023 and August 2024, and followed for 3 months.

Settings and conduct

The measurements will be carried out at the Department of Rehabilitation of “Victor Babes” University of Medicine and Pharmacy Timisoara and at the premises of Red Ortopedic Med in Timisoara. The recovery plan will be carried out in the Department of Rehabilitation, then continued at home.

Participants/Inclusion and exclusion criteria

This study includes patients who underwent surgical treatment for tibial pilon fractures. Patients must be adults who have undergone surgery for unilateral tibial pilon fracture; must show clinical and radiological evidence of fracture healing; must be able to put full weight on the fractured leg.Exclusion criteria: history of traumas or fractures in the lower leg with the tibial pilon fracture, a history of traumas or fractures in the opposite lower leg used as healthy control, any neurological or other health conditions that may cause difficulty in compliance, walking or changes in muscle function.

Intervention groups

Carbon foot orthoses with full reinforcement will be specially designed to correct the asymmetries discovered on the first set of measurements. The entire rehabilitation program will last for 3 months, with a frequency of 5-7 times per week. Each session will last between 30 to 45 minutes.

Main outcome variables

The primary outcomes will be gait, balance, calf muscle properties and muscle strenght. The secondary outcomes will be the quality of life and the severity of pain during sports and daily activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230813059137N1**
Registration date: **2023-08-28, 1402/06/06**
Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**
Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

ANDREI Bolovan

Name of organization / entity

Victor Babes University of Medicine and Pharmacy Timisoara

Country

Romania

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+40 743 505 902

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-01, 1402/07/09

Expected recruitment end date
2024-08-01, 1403/05/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of foot orthoses and exercise program in improving gait, balance and ankle muscle properties in patients after tibial pilon fracture surgery

Public title
Comparison of exercise program and foot orthoses versus exercise program in patients after tibial pilon fracture surgery
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
patients must be adults who have undergone surgery for unilateral tibial pilon fracture; must show clinical and radiological evidence of fracture healing; must be able to put full weight on the fractured leg;; must agree to participate voluntarily healthy contralateral lower leg that can be used as a healthy control;
Exclusion criteria:
history of traumas or fractures in the lower leg with the tibial pilon fracture; a history of traumas or fractures in the opposite lower leg used as healthy control any neurological or other health conditions that may cause difficulty in walking or changes in muscle function lower leg asymmetry not related to the tibial pilon fracture psychiatric disorders or other disorders that affect compliance
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed directly after baseline assessment by a researcher who was not involved in the recruitment of participants using a computer-generated random sequence table. The participants will be randomized into 2 groups at a proportion of 1:1 with 18 patients allocated into each group (Group 1: patients who use foot orthoses and follow rehabilitation program, Groupt 2: patients who follow the rehabilitation program only). Because of the nature of the interventions, it will be impossible to blind the therapists and patients involved in the study.
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
Ethics Committee of the Victor Babes University of Medicine and Pharmacy Timisoara
Street address
Eftimie Murgu Square, No. 2
City
Timisoara
Postal code
300041
Approval date
2023-08-25, 1402/06/03
Ethics committee reference number
26/25.08.2023

Health conditions studied

1

Description of health condition studied
Fracture of lower end of tibia
ICD-10 code
S82.3
ICD-10 code description
Fracture of lower end of tibia

2

Description of health condition studied
Other abnormalities of gait and mobility
ICD-10 code
R26.8
ICD-10 code description
Other abnormalities of gait and mobility

Primary outcomes

1

Description
The primary outcomes will be gait, balance, calf muscle properties and muscle strenght.
Timepoint
The evaluation of the primary outcome following the application of intervention is after 3 months.
Method of measurement

The assessment involves four different testing procedures: myotonometry, muscle strength testing, gait analysis, and double-leg and single-leg balance tests.

Secondary outcomes

1

Description
The secondary outcomes will be the quality of life and the severity of pain during sports and daily activities.
Timepoint
Secondary outcome will be measured 3 months after the application of intervention.
Method of measurement
Assessment questionnaires such as Olerud-Molander Ankle Score (OMAS) and visual analogue scale (VAS) will be used.

Intervention groups

1

Description
Intervention group 1: that will wear foot orthoses in addition to physical exercise
Category
Treatment - Devices

2

Description
Intervention group 2: will only perform physical exercise training.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
„Pius Brinzeu" County Emergency Hospital Timisoara
Full name of responsible person
ANDREI-DANIEL BOLOVAN
Street address
No 156, Liviu Rebreanu Blvd., Timisoara
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ortopedie@hosptm.ro

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
"Victor Babes" University of Medicine and Pharmacy Timisoara, Romania
Full name of responsible person
Constanta-Elena Amaricai
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amaricai.elena@umft.ro
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
"Victor Babes" University of Medicine and Pharmacy Timisoara, Romania
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
"Victor Babes" University of Medicine and Pharmacy Timisoara, Romania
Full name of responsible person
Andrei-Daniel Bolovan
Position
PHD student
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data, representing information about the subjects (baseline, age, gender, height, weight, an-amnestic data), as well as the results of the assessments, will be kept and stored within the De-partment of Rehabilitation, Physical Medicine and Rheumatology of the "Victor Babes" University of Medicine and Pharmacy Timisoara. The results of the study will be disseminated through the publication of articles in peer-reviewed journals, ensuring the confidentiality of the subjects (no publication of subjects' personal data, photographs or video recordings). Essential documents (subject data, evaluation results) must remain complete and legible throughout the data retention period. The data retention period is 10 years from the end of the study.

When the data will become available and for how long
The data will become available at the end of the study. The data retention period is 10 years from the end of the study.

To whom data/document is available
The data is available only for people working in academic institutions and only for research purposes.

Under which criteria data/document could be used
The data can be used only for research purposes.

From where data/document is obtainable
The data/documents are obtainable from the Department of Rehabilitation, Physical Medicine and Rheumatology of the "Victor Babes" University of Medicine and Pharmacy Timisoara.

What processes are involved for a request to access data/document
To obtain data access approval for research or health service assessment projects, requestors must complete our Data Access Request Form and submit supporting documentation (i.e., project proposal, research ethics board submission (if applicable), CV, etc.).. A Data Access Request may be made by one of the following methods: email, fax, mail or at the secretary of the department.

Comments