

# 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 strength. 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

##### Phone

+40 743 505 902

##### Email address

andrei.bolovan@umft.ro

##### 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, Group 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 strength.

**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

##### City

TIMISOARA

##### Postal code

300723

##### Phone

+40 743 505 902

##### Email

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

##### Street address

no. 2 Eftimie Murgu Square, Timisoara

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##### Phone

+40 256 204 250

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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 scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

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## Person responsible for updating data

### Contact

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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**