

# Infection and non-union of the upper and lower part of the shinbone: treatment with the Ilizarov method

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<b>Registration date</b> 25/01/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/12/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An infected non-union (not fully healed) fracture in the lower or distal part of the tibia (shinbone) is a rare condition that can be disastrous. The neighbour joint could be affected and the bone axis could alter. Patients with this condition have to cope with pain, limited physical activity, inability to work and low quality of life. The goal of any surgical treatment is the eradication of the infection, dealing with any bone loss and the healing of the fracture. All the above should be planned and done at the same time. In case of treatment failure even amputation of the limb is an option. In this study, the Ilizarov method, a type of external fixation with circular frames, will be tested.

### Who can participate?

Patients with an infected non-union fracture in the upper or distal part of the tibia

### What does the study involve?

All participants undergo treatment of non-union and infection after surgical cleansing, antibiotic treatment and placement of the Ilizarov apparatus. The patient's clinical and functional outcomes and feelings of pain are measured before the surgery and afterwards throughout the follow-up period at regular intervals. The duration of follow-up is 36 months (3 years).

### What are the possible benefits and risks of participating?

The goal of the treatment is fracture healing and infection eradication. This will improve the quality of life of the participant (return to work, return to daily or sports activity). Other options for these patients include arthrodesis (fusions of the bones resulting in a knee or ankle without any range of motion) or even amputation. As the Ilizarov method is approved and known for 80 years possible risks will not arise from the treatment itself but from the patients' other illnesses and the common risks of any other surgery.

### Where is the study run from?

June 2020 to June 2024

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
1. Prof. Andreas Panagopoulos, andpan21@gmail.com  
2. Dr Konstantinos Sidiropoulos, kcdroq@yahoo.gr

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

University of Patras, School of Medicine 20-11-2020, 5141/38886

## **Study information**

**Scientific Title**

Treatment of septic metaphyseal non-union of tibia using the Ilizarov method

**Acronym**

SePseT Ilizarov

**Study objectives**

The Ilizarov apparatus completely and successfully treats septic pseudoarthrosis proximal and distal tibia metaphysis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 30/09/2020, the General Hospital of Serres Ethics and Scientific Committee (3rd Km Serron-Dramas, Serres, Greece, 62100; +30 (0)2321094549; gnserrres@hospserres.gr), ref: 09/21-09-2020
2. Approved 04/09/2020, the General Hospital of Drama Ethics and Scientific Committee (57 Ippokratous Street, 66100, Drama, Greece; +30 (0)25213 50300; iatriki.upiresia@dramahospital.gr), ref: 336/2020

**Study design**

Multicenter interventional non-randomized trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Patients with closed epiphyses with metaphyseal non-union in tibia which are infected with pathogens

## **Interventions**

The intervention studied is the treatment of pseudoarthrosis and infection after surgical cleansing, antibiotic treatment and placement of the Ilizarov apparatus. The patient's clinical and functional outcomes are taken into account as well as subjective feelings of pain and the change of all these preoperatively and postoperatively throughout the follow-up period at predetermined regular intervals. The duration of follow-up is 36 months (3 years).

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

1. Treatment success assessed using:
  - 1.1. Healed fracture/non-union assessed using x-rays at pre-op, every month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
  - 1.2. Eradication of infection assessed using biomarkers (CRP, ESR, white blood count) at pre-op, every month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
2. Treatment failure will be assessed by clinical examination and radiological evaluation monthly postoperatively until Ilizarov removal (end of the treatment period) and once per semester until the end of the follow-up period (3 years)
3. Side effects will be recorded when they appear either with modification of antibiotic therapy or calibration and cleaning of the Ilizarov device

## **Secondary outcome measures**

1. Functionality of the limb calculated with the AOFAS score/KOS-ADSL (Greek version) at pre-op, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
2. Quality of life assessed with the Short Form-12 (Mental Health) at pre-op, 3 months, 6 months, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
3. General lower limb condition measured using the AAOS Lower Limb Core Scale at pre-op, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
4. Pain measured using the Visual Analog Pain scale once per month until the removal of Ilizarov device and once each semester until the end of the follow-up period
5. Quality of life measured using QALY analysis and the Time Trade-off index at pre-op, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years), and EQ-5D-3L at pre-op, 3 months, 6 months, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)
6. Limb discrepancy, where it exists, measured clinically, radiologically and functionally with the use of wooden wedges (use of the ASAMI score for bone health and function of the limb) at pre-op, 3 months, 6 months, 1 month after Ilizarov removal and every 6 months up to the end of the follow-up period (min. 3 years)

## **Overall study start date**

30/06/2020

**Completion date**

30/06/2024

## Eligibility

### Key inclusion criteria

The participants in the study:

1. Must have completed their skeletal development by closing the epiphyses in the proximal and distal metaphysis of the tibia
2. Have septic pseudoarthrosis at the examined points
3. Freely consent to this study

Patients with concomitant health problems or immunosuppressed ones are not excluded from the study as long as they meet the above criteria

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

11

### Key exclusion criteria

1. Underage patient or open epiphyses
2. Absence of infection
3. Infected non-union in another part of the tibia or anywhere else
4. No signed consent form

### Date of first enrolment

01/12/2020

### Date of final enrolment

31/12/2023

## Locations

### Countries of recruitment

Greece

### Study participating centre

General Hospital of Serres

2nd Km Serron-Dramas

Serres

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Hospital/treatment centre

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<http://www.pgnp.gr/>

**ROR**  
<https://ror.org/03c3d1v10>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

31/10/2024

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to 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?
<a href="#">Protocol article</a>		29/12/2022	30/12/2022	Yes	No