ISRCTN30905788 https://doi.org/10.1186/ISRCTN30905788

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

Submission date
18/01/2022

Recruitment status
No longer recruiting

Registration date
25/01/2022

Overall study status
Completed

Last Edited
30/12/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Type(s)
Principal Investigator

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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; gnserres@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
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Study participating centre
General Hospital of Drama
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
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?
Protocol article		29/12/2022	30/12/2022	Yes	No