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Comparison of the results of two treatment systems in ankle injuries

Submission date
22/10/2021

Recruitment status
No longer recruiting

Registration date
01/11/2021

Overall study status
Completed

Last Edited
01/11/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Syndesmotic injuries are injuries to the ligaments that connect the bones of the lower leg to the ankle joint. The current gold standard treatment for these is screw fixation where the bones are screwed together. However, this leads to problems due to the limited movement of the joint. Newer such devices as flexible TighRope Knotless have been developed which allow healing to take place without the use of screws.
The aim of this study is compare screw fixation with flexible fixation.

Who can participate?
Patients with a syndesmosis injury combined with an ankle fracture identified by clinical examination and X-ray

What does the study involve?
Participants will be randomly allocated to receive either dynamic (TighRope Knotless) or static fixation (Screw). Follow up is at 3, 6 and 12 months following surgery.

What are the possible benefits and risks of participating?
TighRope Knotless does not require a knot reducing wound complications related to the suture knot reported in previous studies performed with classic TighRope. This reduces risks related to a second surgery such as loss of reduction or infection.

Where is the study run from?
University Hospital Infanta Sofía, Madrid (Spain)

When is the study starting and how long is it expected to run for?
March 2019 to November 2023

Who is funding the study?
Foundation of Spanish Trauma and Orthopedic Surgery Society (SECOT).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Código HULP 5242

Study information

Scientific Title

Clinical and functional results of screws and TighRope Knotless device in the treatment of syndesmosis acute injuries: a randomized controlled trial

Study objectives
New-generation suture button device (TighRope Knotless) would provide similar results as screw fixation in syndesmosis injuries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2019, Ethics committee of the University Hospital LA PAZ (P.º de la Castellana, 261, 28046 Madrid, Spain; +34 91 727 75 30; secretariatecnica@idipaz.es), ref: 5242

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of syndesmosis injury

Interventions
During surgery, once bone fractures have been fixed, the lesion of syndesmosis is verified by performing an external rotation stress test with the radiological study. If the patient suffers a syndesmosis injury, we open a randomization envelope and treat the injury with the corresponding implant: screw or tighrope.
All patients in both treatment groups are treated with a splint postoperatively for two weeks. Afterwards, mobilization without load is allowed for a month and then progressive load begins. Until six months after surgery, impact sports activities are not authorized. All patients are reviewed two weeks after the intervention, one month, and at 3,6 and 12 months.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
TighRope Knotless

Primary outcome(s)
1. Pain is measured using Visual Analogue Scale (VAS) at 3, 6 and 12 months
2. Functional outcome is measured using AOFAS Scale and Olerud-Molander scale at 3, 6 and 12 months

Key secondary outcome(s))

1. Ankle range motion measured using manual goniometer at 3, 6 and 12 months
2. Syndesmosis reduction measured usind rx at 3, 6 and 12 months and CT at baseline
3. Complications are collected during follow-up

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Patients over 16 years all with physis closed
2. Patients with acute isolated syndesmosis disruption and patients with ankle fracture associated with syndesmosis disruption

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Patients with physis opened
2. Patients with previus injuries about ankle
3. Patients unable to perform postoperative treatment adequately

Date of first enrolment
01/04/2019

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Infanta Sofía
Paseo de Europa, 34.

San Sebastián de los Reyes
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Sponsor information

Organisation
Hospital Universitario Infanta Sofía

ROR
https://ror.org/05dfzd836

Funder(s)

Funder type
Research organisation

Funder Name
Foundation of Spanish Trauma and Orthopedic Surgery Society (SECOT)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository
All the data will be collected by specialists of the Foot and Ankle Unit of Infanta Sofía University Hospital. A double dissociated database will be created in Excel format with the function of safeguarding the confidentiality of patients.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	01/02/2019	01/11/2021	No	Yes