

# Comparison of the results of two treatment systems in ankle injuries

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/11/2021	<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

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?

Patricia Morales Muñoz, MD, [patrmorales@hotmail.com](mailto:patrmorales@hotmail.com)

## Contact information

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## Additional identifiers

### 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 previous 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.

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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?
<a href="#">Participant information sheet</a>	version 2	01/02/2019	01/11/2021	No	Yes