

# Effectiveness of steroid and local anesthetic injection for patients with functional ankle instability

<b>Submission date</b> 08/01/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Steroid injection is a common treatment for musculoskeletal diseases. However, its effectiveness in functional ankle instability (FAI, a floppy loose ankle) is still controversial. The aim of this study is to find out whether a steroid and local anesthetic injection into the ankle improves ankle function more than health education.

### Who can participate?

Patients aged 18 to 50 years with FAI

### What does the study involve?

Participants are divided into two groups: the steroid group receives a steroid and local anesthetic injection, and the saline group receives a saline injection. For both groups, the follow-up is at 4, 8 and 12 weeks later.

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

Possible benefits include improvement in ankle function, and risks may include injection site infection and local soft tissue damage.

### Where is the study run from?

Huashan Hospital, Fudan University (China)

### When is the study starting and how long is it expected to run for?

January 2022 to January 2023

### Who is funding the study?

National Natural Science Foundation of China

### Who is the main contact?

Dr Yungu Chen, [yungu\\_chen@163.com](mailto:yungu_chen@163.com)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Yungu Chen

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

Clinical effectiveness of intra-articular steroid and local anesthetic injection for patients with functional ankle instability in the improvement of ankle function compared with health education

## Study objectives

Intra-articular steroid and local anesthetic injection improves ankle function more than health education

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 04/01/2022, Huashan Institutional Review Board (12 Middle Wulumuqi Road, Shanghai, China; +86 (0)21 5288045; licaihong199505@163.com), ref: KY2022-070

## Study design

Single-center interventional single-blinded randomized controlled trial

## Primary study design

Interventional

**Study type(s)**

Treatment

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

Functional ankle instability

**Interventions**

Current interventions as of 07/02/2023:

Randomization process: Patients are randomly assigned to two groups by an independent physician by choosing one of two sealed opaque envelopes. The allocation is performed by an independent researcher without knowing the treatment details.

Participants are divided into two groups: the steroid group receives an intra-articular steroid and local anesthetic injection (a mixture of 1 ml of 40 mg/ml triamcinolone and 2 ml 2% lidocaine) immediately after the baseline measurement, and the saline group receives a saline injection immediately after baseline measurement.

For both groups, the follow-up is at 4, 8 and 12 weeks after baseline measurement.

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Previous interventions:

Randomization process: Patients are randomly assigned to Group A, B or C by an independent physician by choosing one of three sealed opaque envelopes containing letters A to C, reflecting the three groups, respectively. The allocation is performed by an independent researcher without knowing the treatment details.

Participants are divided into three groups: group A receives health education, group B receives an intra-articular steroid and local anesthetic injection (a mixture of 1 ml of 40 mg/ml triamcinolone and 2 ml 2% lidocaine) immediately after the baseline measurement, and group C receives a saline injection immediately after baseline measurement.

For all three groups, the follow-up is at 4, 8 and 12 weeks after baseline measurement.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Triamcinolone, lidocaine

**Primary outcome(s)**

Pain is measured using a visual analogue scale (VAS) at baseline, 4, 8 and 12 weeks

**Key secondary outcome(s)**

1. Ankle function is measured by the Cumberland Ankle Instability Tool (CAIT) at baseline, 4, 8 and 12 weeks
2. Balance performance is measured by a center of pressure (COP) forceplate at baseline, 4, 8 and 12 weeks

**Completion date**

31/01/2023

## Eligibility

**Key inclusion criteria**

1. Aged 18 to 50 years
2. At least one episode of significant ankle sprain sustained no less than 12 months prior to the recruitment
3. At least one interrupted day of desired physical activity
4. Existing residual symptoms including recurrent ankle sprains, and/or at least two episodes of sprains and/or perceived ankle instability in the previous 6 months
5. Cumberland Ankle Instability Tool (CAIT) scores lower than 24

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. A history of fracture requiring realignment or musculoskeletal surgery in either lower extremity
2. Osteoarthritis in either lower extremity, head trauma, inner ear disease, muscular dystrophy, or other conditions that could affect balance control
3. A history of acute injury to the lower extremity within 3 months before the enrollment

**Date of first enrolment**

01/10/2022

**Date of final enrolment**

30/10/2022

## Locations

**Countries of recruitment**

China

**Study participating centre**  
**Huashan Hospital, Fudan University**  
12 Middle Wulumuqi Road  
Jingan District  
Shanghai  
China  
200040

## Sponsor information

**Organisation**  
National Natural Science Foundation of China

**ROR**  
<https://ror.org/01h0zpd94>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Natural Science Foundation of China

**Alternative Name(s)**  
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
China

# Results and Publications

## **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available on request from Prof. Xin Ma (prof.xin.ma@qq.com).

The type of data: all electronic Excel data used in the study

Date of availability: after publication in a journal

Whether consent from participants was required and obtained: All participants are required to provide written informed consent

Comments on data anonymization: All data are anonymized

Any ethical or legal restrictions: This study strictly complies with the local ethical and legal regulations

## **IPD sharing plan summary**

Available on request