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

Submission date	Recruitment status	Prospectively registered
08/01/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/01/2023	Completed	Results
Last Edited	Condition category	Individual participant data
07/02/2023	Musculoskeletal Diseases	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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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.

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 Wěiyuánhuì, , 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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes