ISRCTN51678104 https://doi.org/10.1186/ISRCTN51678104

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

Submission date
08/01/2023

Recruitment status
No longer recruiting

Registration date
11/01/2023

Overall study status
Completed

Last Edited
07/02/2023

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
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
Dr Yungu Chen

ORCID ID
http://orcid.org/0000-0002-8486-8098

Contact details
12 Middle Wulumuqi Road
Shanghai
China
200040
+86 (0)21 52889999
yungu_chen@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

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

Secondary outcome measures
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

Overall study start date
04/01/2022

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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

Sponsor details
83 Shuangqing Road
Haidian District
Beijing
China
100085
+86 (0)10 62317474
support@nsfc.gov.cn

Sponsor type
Government

Website
https://www.nsfc.gov.cn

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

Publication and dissemination plan
Planned publication in a high-impact foot and ankle specialist journal

Intention to publish date
05/02/2023

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