Does arthroscopic anatomic repair of the anterior talofibular ligament provide equal functional outcome compared to open anatomic repair in patients with chronic ankle instability: a multicentre randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON50173

Source
ToetsingOnline

Brief title
CAISR Trial

Condition

- Tendon, ligament and cartilage disorders

Synonym
Chronic ankle instability, persisting ankle instability

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,BioMet

Intervention

Keyword: ankle, chronic, instability, surgery

Outcome measures

Primary outcome

The main study parameter is a change in FAOS score of 10 points. This is measured using a questionnaire containing the foot and ankle outcome score (FAOS), numeratic rating scale (NRS) and Cumberland ankle instability tool (CAIT). The primary outcome measures are pain, disability and degree of experienced ankle instability, using. Assessment is performed pre-operatively, and at 3- and 6-months postoperatively.

Secondary outcome

Secondary study parameters are a negative anterior drawer test and normal ROM. The anterior drawer test is registered per mm (range 0-15mm) displacement. ROM is registered in degrees of dorsi- and plantarflexion and is measured using a goniometer. Assessment is performed pre-operatively, and at 3- and 6-months postoperatively.

Additionally we measure complications and recurrence of instability.

Study description

Background summary

Lateral ankle ligament injuries may be a result of ankle sprains. In 10-30% of patients with lateral ankle ligament injuries, chronic lateral ankle instability may be present. If conservative treatment fails, instability is treated surgically. The Bröstrom-Gould procedure is the current golden standard for surgical treatment of chronic ankle instability. This technique is performed both arthroscopically and open. Which approach is better, has not yet been researched.

Study objective

The main purpose of this study is to compare the functional outcome after arthroscopic and open anatomic repair in patients with chronic lateral ankle instability, and secondly assess ankle stability and ankle Range of Motion (ROM) after arthroscopic and open ligament repair.

Study design

A Non-Blinded Prospective Randomized Controlled Trial

Intervention

Both groups of patients are surgically treated by means of the Bröstrom-Gould technique. One group is treated by arthroscopic approach and the second group is treated by the open approach

Study burden and risks

Patient burden is mainly due to extra visits to the outpatient clinic. Pre-operatively the patient will be asked to fill out a questionnaire, and the anterior drawer test and ROM will be checked. Post-operatively the patient will be asked to visit the outpatient clinic 2 more times (3- and 6-months postoperatively) additional to the regular check-ups.
The risk of the investigational treatment is minimal, due to the fact that both treatments, open and closed ligament repair, are currently used in clinical practise and both provide clinically good results. Additional risks/complications associated with ankle surgery can be bleeding, infection, venous thrombosis, over- and under correction, instability recurrence, pain, swelling, reduced ROM and damage to superficial nerves.
Patients may benefit from participation as they are more closely followed-up over time compared to regular procedures. They will receive a standard treatment for ankle instability (open or arthroscopic), but will be assessed 2

extra times up till 6 months after surgery. This way it is easier for patients to indicate (new) complaints and complications.
Patients in the open treatment group might experience more wound complications. This, however, is not yet proven, as is which technique is superior and therefor this study will be performed. To study the two different techniques, their outcomes and complications, to ensure patients will not be unnecessarily exposed to unwanted or side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients are 18 years or older;
- Experience pain and/or a sensation of instability during sports and/or daily activity;

- Isolated lateral ankle instability;
- Planned for surgical repair of the ATFL;
- At least one previous episode of an ankle inversion sprain;
- Complaints for at least 6 months;
- Failed previous conservative treatment

Exclusion criteria

- Serious concomitant injury
- Acute foot or ankle fracture;
- Previous foot or ankle surgery;
- Osteochondral defect (OCD) of the talus with a diameter of >2cm treated using other techniques than bone marrow stimulation (BMS)
- ROM restriction of >10 graden;
- Medial instability
- Severe misalignment;
- Ankle/foot deformities
- Systemic comorbidity leading to delayed recovery
- (general) Hyperlaxity
- Inability or unwillingness to provide consent
- Present factors that may cause difficulty of follow-up

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-02-2017
Enrollment:	35

Type:	Actual

Ethics review

Approved WMO Date:	03-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55707.018.16