Lateral ligament repair for ankle instability protected with internal bracing. A multicenter, randomized controlled trial.

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To evaluate if patients with chronic, recurrent lateral ankle instability who are treated with surgical lateral ankle ligament repair protected with an internal brace, have significant better ankle function after surgery compared to patients treated...

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

Summary

ID

NL-OMON54817

Source
ToetsingOnline

Brief title
the STRONG-study

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
ankle instablity, ankle sprain

Research involving
Human

Sponsors and support

Primary sponsor: Sint Annaziekenhuis
Source(s) of monetary or material Support: Eigen middelen

Intervention

Keyword: ankle instability, ankle ligament reconstruction, internal brace

Outcome measures

Primary outcome

The difference in FAOS score three months after surgery between the

Intervention Group and the Control Group is the main study endpoint.

Secondary outcome

Secondary endpoints are the incidence of recurrent ankle inversion trauma

within one year after surgery and differences in subjective and objective ankle

stability, motor control, pain, ankle function and satisfaction with the

treatment between the IG and the CG. This will be determined by means of

questionnaires, physical examination and clinimetric testing.

Study description

Background summary

Ankle inversion trauma often leads to chronic ankle instability which can severely limit the patient during daily activities, including work and sports. When conservative treatment fails, surgical treatment in which the ruptured anterior talofibular ligament (ATFL) is reconstructed can be considered. Surgical treatment for ankle instability is associated with a relatively long rehabilitation due to the initial limited strength of the reconstructed ligament. This limited strength in the first weeks after surgery makes it necessary to protect the reconstructed lateral ankle ligament with immobilization. Usually a lower leg plaster is applied for six weeks. Due to the initial limited strength of the reconstructed ligament and the immobilization period itself, return to activities after surgery for this

injury usually takes up to six months or even more. Therefore, surgical intervention is only indicated for patients who suffer chronic, recurrent ankle instability.
With a new surgical technique, an internal brace is placed over the reconstructed lateral ankle ligament, thereby providing protection which makes immobilization in the postoperative weeks unnecessary. This allows an earlier start of the rehabilitation which in theory should result in patients being able to return to activities earlier after surgery. Also, adding an internal brace to the reconstructed lateral ankle ligament might result in a lower recurrence rate of ankle instability compared to the current surgical procedure.

Study objective

To evaluate if patients with chronic, recurrent lateral ankle instability who are treated with surgical lateral ankle ligament repair protected with an internal brace, have significant better ankle function after surgery compared to patients treated with standard surgical lateral ankle ligament reconstruction without internal brace. The appropriately adapted rehabilitation for each surgery procedure is applied.

Study design

Multicenter randomized controlled trial (RCT).

Intervention

The Intervention Group (IG) has surgery to reconstruct the anterior talofibular ligament with an internal brace placed over the reconstructed ligament in the same surgical session. After surgery patients will receive physiotherapy treatment using an accelerated rehabilitation protocol. The Control Group (CG) receives the same operative treatment but without internal brace. After a six week immobilization period they will receive physiotherapy treatment in accordance with current national guidelines.

Study burden and risks

Both groups will undergo surgical treatment. Patients will be admitted to the hospital on the day of the surgery, and they will be discharged the same day or the following morning if no complications occur. Patients in the Intervention Group start physiotherapy within one week after surgery and will have a follow up visit at 2, 6 and 12 weeks and at 6 and 12 months after the surgery.
Potential risks and complications of all surgery procedures include swelling, infection, pain, wound dehiscence and nerve damage. Standard hospital protocols will be applied to minimize these risks. Specific risks and complications associated with placing the internal brace are overtightening of the internal

brace resulting in limited ankle range of motion and premature loosening of the internal brace thereby no longer protecting the ankle ligament reconstruction. Both groups will complete questionnaires before treatment and at 6 and 12 weeks, and at 6, 9 and 12 months follow up. Expected benefits from study participation are that the rehabilitation is extra controlled on conductance in accordance with current National guidelines (control group), and for the intervention group we expect a quicker return to physical activity and a lower recurrence rate of ankle inversion trauma. Furthermore by participating in the study the patient will receive more follow up moments compared to standard treatment, which might possibly lead to earlier detection of delayed recovery.

Contacts

Public
Sint Annaziekenhuis

Bogardeind 2
Geldrop 5664 EH
NL
Scientific
Sint Annaziekenhuis

Bogardeind 2
Geldrop 5664 EH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Male or female patient diagnosed with chronic lateral ankle instability (multiple ankle inversion trauma within 12 months and symptoms present >1 year). Lateral ankle instability is present if the patient complains of giving way of the ankle and has positive signs of ankle instability during physical exam (talar tilt score of >15 degrees compared to contralateral ankle or anterior drawer test score of >10mm compared to the contralateral ankle.
- Conservative therapy has failed.
- Normal foot and ankle anatomy as determined by orthopedic surgeon.
- Patients in whom their ankle symptoms interfere with their physical activities.
- Patients between the age of 18 and 60 years.
- Patients with isolated anterior talofibular ligament which is indicated for repair using the Brostrom-Gould technique.
- BMI <=30
- Patients who are able and willing to undergo ankle surgery.
- Patients who are able and willing to comply with the rehabilitation protocol in any of the study physiotherapy centers.
- Patients who are able and willing to return for follow-up evaluations.
- Patients with sufficient understanding of the Dutch language.

Exclusion criteria

- Patients who need concomitant ankle surgery (i.e. Calcaneofibular ligament reconstruction, peroneus tendon repair, arthroscopy of the ankle, etc).
- Patients with comorbidities, including musculoskeletal injuries or diseases in other joints than the affected ankle which limits their physical activity.
- Ankle instability due to abnormal foot and ankle anatomy.
- No objective or subjective ankle instability.
- Previous ankle surgery.
- Patients in which the contralateral ankle also shows lateral ankle instability.

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):	04-12-2018
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-04-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL64224.015.17