The effectiveness of Extracorporeal Shockwave therapy in the treatment of medial tibial stress syndrome*

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Aim of this study is to determine the effectiveness of Extracorporeal Shockwave Therapy (ESWT) on degree of recovery after 3 months in patients with MTSS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37753

Source
ToetsingOnline

Brief title
The effectiveness of ESWT in the treatment of MTSS

Condition

- Other condition

Synonym
Medial Tibial Stress Syndrome, Shin splints

Health condition

bewegingsapparaat, bot

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Efficiacy, Extracorporeal shockwave therapy, Medial Tibial Stress Syndrome, Shin plints

Outcome measures

Primary outcome

Primary outcome measure is degree of recovery after 3 months (using a 5 point

Likert scale). The participants will complete a questionnaire at 4 time points

during the total study period of 29 weeks.

Secondary outcome

Parameters to determine the secondary outcome objectives in this study are:

- Experience of pain in sport activities, activities in daily

life/profession/education (using a numeric rating scale)

- Degree of restrictions in sport activities, activities in daily

life/profession/education (using a 5 point Likert scale)

- Response rates to questionnaires, and adherence/compliance rates,

- Satisfaction of ESWT

- Side effects of ESWT

Study description

Background summary

Medial tibial stress syndrome (MTSS) is one of the most common exercise-induced overuse injuries in runners as well as athletes participating in jumping

sports, such as volleyball and basketball.(1) It can be quite disabling and progress to more serious complications if not treated properly.(1) The injury is characterized by exercise-induced pain in the lower leg with symptoms commonly occurring in the distal third of the posteromedial tibia border. (1, 2)

There is little information available on the recovery time in patients with MTSS. Two recently
published studies did assess recovery time.(3, 4) The mean time to recovery in 35 male recruits was 58 (+/- 27) days.(3) Rompe (2010) showed that time to return to sport was variable and ranged from 6 weeks for some soccer players to 24 weeks for some runners. In military recruits higher BMI will result in a longer time to full recovery, whereas other prognostic indicators such as a previous duration of symptoms, functional activity score, the symptom-free running distance at baseline, increased ankle plantar flexion, decreased internal range of hip motion and positive navicular drop test were not associated with time to recovery.(3)

Until recently, MTSS was thought to be due to a tractioninduced periostitis. However, from
histological studies it is shown that no periostitis is present in patients with MTTS.(5, 6) A recently published systematic review concluded that MTSS is caused by bony overload, with numerous studies supporting this theory.(2) Several imaging studies showed that the tibial cortex is osteopenic and that the bone marrow is involved.(7, 8) Studies on bone density showed that the tibial bone density in MTSS subjects is decreased and that bone density returns to normal values after recovery.(9, 10) The current hypothesis is that the "bone strain" is caused by a failure of adaption to repetitive bending of the tibial bone (2). Therefore, MTSS is an injury in which the tibial bone metabolism is affected instead of the tibial fascia.

The literature supports **rest** as the most important treatment in the acute phase of MTSS.(1) For many athletes prolonged rest from activity is not ideal and therefore other therapies are necessary to help the athlete return to activity quickly and safely.(1)
There is evidence that stimulation with extracorporeal shockwave therapy (ESWT) will positively influence the bone metabolism by stimulation of bone growth factor synthesis in human osteoblasts and fibroblasts (11).

The application of ESWT has already been shown to support the healing in tibial fractures with nonunion.(12) It is therefore reasonable to hypothesize that extracorporeal shock wave therapy can also enhance the healing of tibial stress injuries like MTSS.

References
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Study objective

Aim of this study is to determine the effectiveness of Extracorporeal Shockwave Therapy (ESWT) on degree of recovery after 3 months in patients with MTSS.

Study design

This study is designed as a randomized, placebo-controlled clinical trial with a 6 months follow up. It will have two treatment arms: treatment with ESWT in addition to standard treatment of usual care and a placebo treatment in addition to standard treatment of usual care.

Intervention

76 participants will be randomized to receive either 3 (placebo) ESWT-treatments at a weekly interval, in addition to a standard treatment of usual care (relative rest and resumption of sport activities using an adapted version of the pain monitoring model).

Study burden and risks

The effort of the participants consists of completing a questionnaire at 4 time points during the total study period of 29 weeks. Furthermore, the participants need to visit the Sport medical centre UMCG 3 times. All participants will receive placebo or treatment with ESWT for 3 weeks, at a weekly interval. There is only a very, very small chance that side effects of ESWT will occur. So the potential high benefit and the low risk and burden to the subject justify this relevant study into the effectiveness of ESWT in physical active men and women.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Physical active men and women between 18 and 45 years
- Exercise-induces pain in the leg on the posteromedial border of the tibia
- Pain on palpation of the posteromedial border of the tibia for at least 5 centimeters
- Symptoms for at least 6 weeks
- Unilateral and/or bilateral MTSS

Exclusion criteria

- Clinical signs of tibial stress fracture or compartment syndrome
- Neurovascular disease in the under leg
- Pregnancy
- Malignancy and blood clotting disorders
- The use of anticoagulant drugs or corticosteroids
- The use of pacemaker

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2012
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL38473.042.11