Does military personnel suffering from MTSS benefit from early intervention with ESWT?
A multicentre randomised trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON49560

Source
ToetsingOnline

Brief title
Does military personnel with MTSS benefit from intervention with ESWT?

Condition

- Muscle disorders

Synonym
Medial Tibial Stress syndrome; shinplints

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Defensie

Source(s) of monetary or material Support: alle proefpersoenen;artsen en fysiotherpaueten en betrokken bij dit onderzoek zijn werkzaam bij Defensie. Het onderzoek wordt in werktijd uitgevoerd met materiaal en middelen zoals gebruikelijk binnen het Eerstelijns Gezondheidszorg Bedrijf.

Intervention

Keyword: ESWT, Military personnel, MTSS

Outcome measures

Primary outcome

Primary Objective:

* Covered running distance in 12 minutes (Cooper*s test, a part of the

Defensie Conditie Proef (DCP) with a NPRS score of maximum 3.

Secondary outcome

Secondary Objective(s):

* Time to complete a 5 kilometres march; with a NPRS score of maximum 3 and a

maximum time of 60 minutes

* The MTSS score specifically measures the pain along the inside of the shin

and the limitations arising from this shin pain. The score ranges from 0 (no

limitation) to 10 (full limitation) (12) (Annex 2)

* Pain in general is measured with the Numeric Pain Rating Scale (NPRS). The

score ranges from 0 (no pain) tot 10 (worst pain imaginable) (Annex 3)

* The perceived effect of treatment and satisfaction with the treatment are

measured with Global Perceived Effect questionnaire (GPE). These scores range

for the perceived effect from *very much improved* to *very much deterioration*

and for satisfaction from *Absolutely satisfied* to *Absolutely dissatisfied*.

(13) (Annex 4)

Study description

Background summary

In physically active population Medial Tibial Stress Syndrome (MTSS) is a common overuse injury of the lower leg(s). It is often reported among military personnel and runners. The incidence rates in military personnel are ranging from 7.2% to 35% and in runners from 13.6% to 20% . In the military this injury can lead to withdrawal from the basic military training (Algemene Militaire Opleiding (AMO)) or even discharge from the Royal Netherlands Army (RNLA) if treatment isn*t successful.
MTSS is characterised by pain, sometimes with swelling, on the medial border of the mid and distal third of the tibia. This occurs with physical activities as well as in rest. Treatment and prevention of MTSS are difficult due to lack of understanding of its aetiology. One of the hypothesis is that there is tibial periostitis in conjunction with cortical bone oedema and microtrauma .
Risk factors for MTSS have been studied in many studies Potential risk factors are Body Mass Index (BMI), gait kinematics, Range of Motion (ROM) of the ankle and hip, navicular drop and many others. However, the exact way of how these factors contribute to the development or maintenance of MTSS is still not clear .
Due to the aetiology of MTSS being unknown and a range of potential risk factors, there are many treatment options, but the evidence for effectiveness of these treatments is very weak or absent .
Extracorporeal shock wave therapy (ESWT) is the application of short burst high intensity sound waves. It has been used in the management of insertional tendinopathies as a mechanism to reactivate the local tissue repair response. For MTSS therapeutic use and effectiveness of ESWT is hypothesised to stimulate bone remodelling or to reduce pain signalling to the brain and breaking down calcium deposits. Evidence of the effectiveness of ESWT is weak to moderate, but it appears to be more effective or more promising than other non-surgical treatments for reducing pain in lower extremity disorders
ESWT treatment is usually effective with little treatment sessions. Ideally treatment of MTSS should be as short as possible, as the consequences for military deployment or finishing the basic military training can be dramatic, as it can lead to be declared not fit for duty and possible discharge of the RNLA .
A different part of treatment for MTTS is adjustment in training and exercise. In the RLNA a guideline for lower leg complaints is used for treatment of MTSS. In the RNLA both treatments are usual care. Both of them are used separately as treatment or complementary.
The goal of this study is to examine the effect of both treatment strategies on the running distance of the Defensie Conditie Proef (DCP) and on the time of a 5k march, as these are important indicators whether the soldiers are fit for duty. The goal is to establish whether one of these treatment strategies will

lead to longer (painfree) running distances en faster (painfree) marching times after the first 3 weeks. And if so, will these effects remain after a follow up period of 12 weeks.
If one of the strategies leads to better outcome values, this will lead to possible change of best practice and care for military personnel suffering from MTSS.

Study objective

The goal of this study is to examine the effect of both treatment strategies on the running distance of the Cooper*s test, a part of the Defensie Conditie Proef (DCP) and on the time of a 5k march, as these are important indicators whether the soldiers are fit for duty. The goal is to establish whether one of these treatment strategies will lead to longer running distances en faster marching times after the first 3 weeks. And if so, will these effects remain after a follow up period of 12 weeks. We want to investigate this with the following research parameters:
Primary Objective:
* Covered running distance in 12 minutes (Cooper*s test, a part of the Defensie Conditie Proef (DCP) with a NPRS score of maximum 3.
Secondary Objective(s):
* Time to complete a 5 kilometres march; with a NPRS score of maximum 3 and a maximum time of 60 minutes
* The MTSS score specifically measures the pain along the inside of the shin and the limitations arising from this shin pain. The score ranges from 0 (no limitation) to 10 (full limitation)
* Pain in general is measured with the Numeric Pain Rating Scale (NPRS). The score ranges from 0 (no pain) tot 10 (worst pain imaginable)
* The perceived effect of treatment and satisfaction with the treatment are measured with Global Perceived Effect questionnaire (GPE). These scores range for the perceived effect from *very much improved* to *very much deterioration* and for satisfaction from *Absolutely satisfied* to *Absolutely dissatisfied*.

Study design

Pilot Multicentre Randomised Clinical Trial

Intervention

Trainings GeneeskundeTrainings Fysiologie (TGTF) guideline for MTSS (Annex 1) versus Focussed ESWT (3x, max 1x week) added to this TGTF guideline in the first 3 weeks.

Study burden and risks

After the eligibility test, participants come to the health centre at the

barracks for treatment during a 16-week period.
In addition to the normal physiotherapeutic information that is mandatory in a treatment file, the following additional information is collected:
* Height and weight are measured in week 1
* The shock wave treatments take place weekly in weeks 1 to 3.
* In the first, 3rd, 15th week a Cooper*s test is performed as well as a 5 km march.
* Two questionnaires (NPRS and MTSS) are completed in week 1, after 3 and 15 weeks. The GPE is added in the 3rd and 15th week.

During this research the usual care for MTSS is being evaluated. The provided care (di-agnostics, intervention and guidance) does not differ from the care that subjects would receive if they chose not to participate in this research. ESWT as well as exercise pro-grams are effective for treating pain and improving function for MTSS complaints. Occa-sionally, patients do not (fully) recover. Shockwave treatment can be experienced as painful.
The recommended ISMST focussed ESWT parameters for MTSS are 1500-2500 pulses, energy flux density (EFD) 0.10-0.25 mJ/mm²(pain-adapted dosing) and standard up to 3 max. 5 treatments with an interval of 1-2weeks.
From data used in previous studies combined with consensus of professional experience from treatment of MTSS we will be using 1500 pulses with EFD 0.10 and 0.25 mJ/ mm² and 3 treatment sessions. As shockwave treatment can be as experienced as painful, the subject, together with the therapist, chooses an intensity between EFD 0.10 and 0.25 mJ/ mm² that can be maintained during the 1500 pulses. In addition to short-term redness of the skin, no side effects have been reported from shockwave

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

Military men and women in active duty
18-60 years old
MTSS criteria as described by Yates and White (4):
o palpable pain, localized to the posteromedial tibial border of the tibia that occurs during exercise, excluding pain from ischaemic origin or signs of stress fracture
Be fluent in reading, speaking and understanding Dutch language

Exclusion criteria

Fracture of the lower leg < 12 months
Current treatment for lower leg complaints
Meeting contra- indications for ESWT (Focused waves with low and medium energy):
o Malignant tumour in the treatment area (not as underlying disease)
o Pregnancy
Not accepting informed consent
Achilles disorders (pain and swelling in the Achilles tendon)
Chronic Exertional Compression Syndrome (CECS; pain on the outside of the shin)
Deep Vein Thrombosis (DVT)
Decreased sensitivity in the lower leg
Earlier treatment of the lower leg with ESWT shorter than 4 months ago.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2020
Enrollment:	84
Type:	Actual

Medical products/devices used

Generic name:	Extracorporeal Shockwave Therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-10-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL74754.028.20