Assessment of local tibial bone health in an athletic population at risk for medial tibial tibial stress syndrome: a prospective cohort study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON40670

Source
ToetsingOnline

Brief title
Local tibial bone health in athletes: a prospective cohort study

Condition

- Bone disorders (excl congenital and fractures)

Synonym
shin splints

Research involving
Human

Sponsors and support

Primary sponsor: Bergman Clinics

Source(s) of monetary or material Support: Er is geen geldstroom voor deze studie;dit onderzoek wordt op 'vrijwillige basis' verricht door de onderzoekers.

Intervention

Keyword: Athletes, Cohort study, MTSS, Tibial bone health

Outcome measures

Primary outcome

Incidence of MTSS

Local tibial bone health as expressed in "Speed of Sound" (meters / seconds)

Secondary outcome

Those subjects that develop MTSS are asked to fill out the newly developed

patient reported outcome measure "The MTSS-score". This outcome measure

consists of items that evaluate pain, pain and limitation in activities of

daily life and sports activities.

Reliability study:

Intraclass correlation coefficient for intra-rater and inter-rater reliability

Standard error of measurement

Smallest detectable change on the individual and group level.

Study description

Background summary

Medial tibial stress syndrome (MTSS) is the most frequently seen lower leg injury in athletes and military personnel . MTSS is defined as "exercise-induced diffuse pain along the posteromedial border of the tibia"

that is provoked by palpation over a length of 5 or more consecutive centimetres.
Presently, MTSS is thought to be caused by bony overload .This theory is based on a case-control and a follow-up study by Magnusson et al.. They found a reduced bone mineral density in the tibia in chronic MTSS patients (mean duration of complaints: 31 months) compared with healthy athletic controls. On follow-up, when symptoms had disappeared, the bone mineral density was restored . In contrast with these results, Özgürbüz et al. found no differences in bone mineral density between MTSS patients with a short period of complaints (mean duration: 5 weeks) and active controls. As subjects' tibial bone health has never been studied prior to and during the onset of MTSS, it remains unclear how MTSS is related to changes in local tibial bone health. For treatment and prevention, it could be important to clarify MTSS' pathophysiology.
Quantitative Ultrasound (QU) is a commonly used device for measuring bone health. A probe, with a transmitter and receptor, sends (and receives) sound waves through bone tissue. The speed on which the wave travels through bone is called Speed of Sound and is an indication of bone health. In osteoporosis research it has been shown to accurately predict the onset of osteoporosis and fractures. QU is a good technique to use as it is a non-invasive, safe technique without radiation. Therefore, it could be used frequently to monitor local tibial bone health. QU has shown to be reliable and valid in osteoporosis research. As MTSS's pathophysiology is hypothesized as of bony origin, QU may be of predicting value for healthy populations at risk for MTSS.
If MTSS appears be associated with a decreased local tibial bone health and QU is able to measure changes in tibial bone health relevant to MTSS, preventative and curative interventions could be better targeted.

Study objective

The aim of this prospective cohort study is threefold: (1) for a better understanding of MTSS' underlying pathophysiology, (2) to assess the QU's reliability in healthy subjects and subjects with MTSS and (3) to assess the validity of QU in predicting MTSS. In addition, a reliability study will be performed in which inter-rater and intra-rater reliability of the quantitative ultrasound device will be assessed. For this part of the study 20 subjects will be invited to be measured 3 times on one day by two physiotherapists.

Study design

Prospective cohort study. Participants are followed for 4 months. During these months their local tibial bone health is measured every two weeks.

Study burden and risks

MTSS is a common injury among students of the *academie voor lichamelijke opvoeding*. Many of the students are between 16 and 18 years of age. To aim

preventative and curative interventions, it is highly important to clarify MTSS' pathophysciological nature. Furthermore, this study is not accompanied by any risks or harms. This is an observational design. No measurements could affect participants' (emotional) well-being. Participants are subjected to 9 measurements, each taking 5 minutes of the students' time. For those student participating in the reliability study, two additional measurements will be performed on, each taking 5 minutes for each measurement.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All healthy students (>=16 years), without a history of cruris fractures, will be eligible for

inclusion. Those students having lower leg pain within a week prior to study's commencement, will be excluded.

Exclusion criteria

History with crural fractures; lower leg pain within a week prio to study's commencement

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-11-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL49488.100.14