Reviewer's report

**Title:** The treatment of medial tibial stress syndrome in athletes; a randomized clinical trial

**Version:** 1 **Date:** 6 September 2011

**Reviewer number:** 2

**Reviewer's report:**

1. Is the question posed by the authors new and well defined? Yes.
2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work? Yes.
3. Are the data sound and well controlled? Yes.
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes.
5. Are the discussion and conclusions well balanced and adequately supported by the data? Yes.
6. Do the title and abstract accurately convey what has been found? Yes.
7. Is the writing acceptable? Yes

**Problems with the paper:**

a) Introduction: Make more clear that the etiology is still uncertain. I do not agree that the findings in imaging (DEXA, HR-CT) related to osteopenia in the painful part of the tibia lead us to anywhere other than a hypothesis. It is no proof. And I do not agree that it is feasible to deduct a therapy regimen from these findings.

What imaging data were available when you chose an individual for inclusion in the study?
Where imaging parameters different before and at conclusion of the study?
Who funded the study?

b) Methods: How many patients with suspected MTSS were excluded from the study because of stress fracture or CECS? How were these diagnoses confirmed?

Please address exclusion criteria more extensively than in Table 1.
I did not find your promary endpoint anywhere: time to complete a running program (able to run 18 minutes with high intensity)

c) Intake:

You write that your non validated test has used in previous studies, I assume with you as lead author.

What I miss, in the discussion, how the running test in the current study fared in comparison with the pneumatic leg brace (Ref: #32) and shockwave therapy (Ref: #33). Please discuss the results, at least you administered the same test! (though not validated, but there is none)

d) Compliance.

I find your way out of the complaince dilemma fascinating. However, there was no direct supervision of the athletes doing the exercises. Personally I am convinced that when i a study hardly anybody will admit I did not follow the prescription at all. This remains a major weak point in the study design, and I am honestly surprised it passed your ethical committee.

e) Power analysis:

I find it ridiculous to calculate a power based on studies reporting a maximum recovery time of ten to twenty days.

This makes the whole sample size calculation close to worthless. And with it your statistics.

What about a pilot study from your institutions? This would have provided more sound data.

f) Discussion: Be even more critical.

Your study (as many before on this topic) has major flaws:

No validated outcome measure
Diagnosis based on subjective criteria only
Questionable sample size and power calculation
Questionable assessment of compliance
No superior result of any of your treatment measures

So what does your study add to our knowledge? Nothing, unfortunately.
I do not find it adequate to recommend a running program to treat MTSS. Without a resting control group you cannot suggest to treat MTSS with a graded running program alone (page 13, line 296)

Table 3:
Baseline

How many patients had bilateral MTSS? Did you exclude bilateral MTSS? Or count as two cases?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.