Effect of PESF on speedskaters.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22212

Source
NTR

Brief title
EPEFS

Health condition

Sporters, Athletes
Schaatsers, Speedskaters
Schaatsen, Speedskating
Pulserend elektrostatisch veld,
Pulsating electrostatic field (PESF)

Sponsors and support

Primary sponsor: Sponsor Ziekenhuis Tjongerschans
Sponsor GLNP life sciences
Source(s) of monetary or material Support: Fund = sponsor

Intervention

Outcome measures

Primary outcome

To analyse the effect of six weeks PESF treatment on aerobic and anaerobic performance, measured with an maximum exercise test on the bicycle ergometer (VO2max and Wingate

30) in speedskaters aged between 18-23.

Secondary outcome

To analyse the effect of PESF on:

· personal best times in a speedskating competition after four weeks.

· quality of life measured by the RAND-36 questionnaire after six weeks of treatment.

· fatigue (locally in the lower extremity and general) measured by an adapted visual analogue scale during the six weeks of treatment with PESF.

Study description

Background summary

Dutch speedskating teams are innovative and always looking for improvements. Recently pulsating electrostatic field (PESF) treatment has been suggested to improve aerobic performance and reduce exercise induced muscle soreness. The underlying physiological mechanism could be improved peripheral muscle perfusion due to decreased erythrocyte aggregation as well as by increased mitochondrial function. However well-designed studies on this topic are lacking. In the current study, we hypothesize that PESF improves aerobic and anaerobic performance in talented speedskaters.

This is a single center, double-blind randomized controlled trial. Study population: 20 talented Dutch speedskaters between 18-23 years from the regional training centers in Groningen and Heerenveen. All participating on a regional and/or national level, in different kind of distances in long track speedskating. The intervention group will receive one PESF session of 30 minutes weekly during six weeks. The sham group will receive a sham treatment with the modified PESF device which is turned on but has no power output. Participants will undergo two maximal exercise tests at baseline and after six weeks. Besides the exercise challenge the skaters fill in a quality of life questionnaire (RAND-36). Both groups (PESF and sham) will receive once a week a 30 minute treatment preceded by a not invasive measure of body composition. Before each session the skaters will also fill in a form about their feeling of fatigue. During the six weeks of treatment the training load is also registered on a daily base to monitor the equivalence of both groups. The New Health 9000 is able to generate a PESF with intensity between 2000 to 9000V at extremely low current levels at a 50 Hz pulsating frequency. The PESF device is not invasive and has a European safety certificate. To date, no adverse events are reported. If this study demonstrates significant positive effects due to PESF, speedskaters may improve their training conditions and competition results.

Study objective

We hypothesize that PESF improves aerobic and anaerobic performance in talented speedskaters.

Study design

Baseline tests first week: Wingate, VO2max, and Quality of life questionnaire.

Speedskating competition after four weeks.

Final tests in week six: the same as at baseline.

Treatment: will be preceded by measuring body composition. Parameters as bloodpressure, saturation and heartrate will be monitored. Fatigue (locally in lower extremity and general) and possible adverse events will be monitored as well. During the six weeks of treatment the training load is also registered on a daily base. Duration of training was recorded in minutes and perceived exertion was measured on a scale from 1 to 10. Training load is calculated by multiplying duration and perceived exertion scores.

Intervention

Treatment: Pulsating electrostatic field therapy for 6 weeks, one treatment of 30 minutes per week.

Sham: same procedure as treatment group only with a modified device. Which is turned on but has no power output. So the sham has the same features but doesn't work. Dosage is also 30 minutes per week.

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Eligibility criteria

Inclusion criteria

Age 18 years or older.

Skating at a regional and/or national level.

Training a minimum of 6 times per week.

Exclusion criteria

Presence of implanted electronic devices (pacemaker).

Injuries whereby training and competition are different from normal.

Presence of osteosynthesis material (pins, screws, metal plates).

Be treated with similar therapy.

Signs of infection or acute disease.

Possible pregnancy.

Participating in another medical research that will be interfering.

Signs and symptoms of a possible oncological disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-12-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-10-2017
Application type:	First submission

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
NTR-new	NL6633
NTR-old	NTR6819
Other	/ 201700744 - Research register UMCG : M17.220491 - METc UMC

Study results