The effect of nebulised salbutamol and isotonic saline on exercise induced bronchoconsonstriction in elite skaters following a 1500 meter race.

No registrations found.

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

Summary

ID

NL-OMON26511

Source
NTR

Brief title
Omron and elite skaters

Health condition

Elite skaters perform in cold air, an environment which has a low absolute humidity. In training and during competition, when the level of exertion is high, the skater repeatedly breathes cold and dry air, resulting in an inflammation of the lungs similar to that seen in asthma. This inflammation may cause bronchus obstruction after exercise. In order to combat the consequences of performing in dry or unconditioned air, this research makes use of a fully portable ultrasonic nebulizer (OMRON).

Sponsors and support

Primary sponsor: drs. J.M.M. Driessen
Thialfweg 41
8441 PW Heerenveen
Source(s) of monetary or material Support: Sportmedisch Expertisecentrum
Thialfweg 41
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Intervention

Outcome measures

Primary outcome

The effect on the decrease in FEV1 after exercise by ultrasonic nebulization with salbutamol 1 mg or 0.9% sodium chloride (NaCl) (Carlson, et al, 2008, Carlson, et al, 2008) compared to controls with no intervention.

Secondary outcome

1. Analyze the change in airway resistance after exercise, measured with the FOT and the effect of salbutamol on this change compared to, 0.9% NaCl and controls;

2. Analyzing the change in respiratory reactance after exercise, measured with the FOT and the effect of salbutamol on this change compared to 0.9% NaCl and controls;

3. Analyzing the change in electro physiological activity of the respiratory muscle system, measured with EMG with salbutamol on this change compared to , 0.9% NaCl and controls.

Study description

Background summary

Rationale:

Elite skaters perform in cold air, an environment which has a low absolute humidity. In training and during competition, when the level of exertion is high, the skater repeatedly breathes cold and dry air, resulting in an inflammation of the lungs similar to that seen in asthma. This inflammation may cause bronchus obstruction after exercise. In order to combat the consequences of performing in dry or unconditioned air, this research makes use of a fully portable ultrasonic nebulizer (OMRON).

Objective:

To analyze the additional benefits of nebulization with a solution of NaCl or salbutamol after exercise by elite skaters in dry air in comparison to elite skaters not nebulising (controls). Study design: Double dummy, randomized, placebo-controlled design.

Study population:

Group of 41 elite skaters in the 18 to 35 year age group.

Intervention:

Nebulization with 1 mg Salbutamol by means of ultrasonic nebulization after speedskating a distance of 1500 metres. Placebo group nebulization with 0.9% sodium chloride (NaCl); the control group will only complete the 1500 metres.

Main study parameters/endpoints:

Reduced decrease in FEV1 after exercise by the verum group compared to placebo and control groups among elite skaters.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The participants will undergo a lung function test once before and three times after speedskating a distance of 1500 metres. The test consists of FOT and spirometric measurements. Further electromyographic measurements(EMG) take place during and after exercise. These measurements give information on muscle activity of the respiratory muscle system. The 1500 metres speedskating lasts approximately 3 minutes. Nebulization of salbutamol or 0.9% NaCl presents a minimal risk and is standard practice in the study population. The potential obstruction of the airways which may develop after a distance of 1500 metres in dry air can be compared with previous experiences with similar exertion by elite skaters.

Study objective

To analyze the additional benefits of nebulization with a solution of NaCl or salbutamol after exercise by elite skaters in dry air in comparison to elite skaters not nebulising (controls). Reduced decrease in FEV1 after exercise by the verum group compared to placebo and control groups among elite skaters.

Study design

FOT measurements will be performed with R.O.S., Oscilink®, Sensormedics® to measure general respiratory resistance and reactance. FOT measurements will consist of 3 repeated measurements with nose clipped and with hands supporting cheeks and base of the mouth

(Oostveen, et al., 2003). FOT measurements will be performed before and at 10, 15 and 30 minutes after exercise. The average of resistance and reactance values will be used for statistical analysis. A Masterscope® Jaeger®, will be used to measure flow -volume loops in accordance with current ERS/ATS guidelines (American Thoracic society, 1999). Lung function will be calculated from the best curve. Zapletal reference values will be used to calculate the % of the predicted value of the FEV1 (Zapletal & Chalupova, 2003). Flow volumes will be measured in duplicate before and at 11, 16 and 31 minutes after exercise, the best values at each time point retained for analysis. Electrical muscle activity (EMG) of the diaphragm and intercostal muscles was derived transcutaneously from pairs of single electrodes (disposable Neotrode, ConMed Corporation, NY) (Maarsingh et al., 2002). To obtain the electrical activity of the diaphragm, two electrodes were placed bilaterally below the costal margin in the nipple line (frontal lead of diaphragm) and two bilaterally on the back at the same level (dorsal lead of diaphragm). The mean value of the processed data of the frontal and dorsal leads of the diaphragm represented the electrical activity of the whole diaphragm. To obtain the electrical activity of the intercostals muscles, two electrodes were placed each in the second intercostal space left and right, 2 cm parasternal. A common electrode was placed at the height of the sternum.

Intervention

Nebulization with 1 mg Salbutamol by means of ultrasonic nebulization after speedskating a distance of 1500 metres. Placebo group nebulization with 0.9% sodium chloride (NaCl). The control group will only complete the 1500 metres.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 35 years;

2. Elite speedskater;

3. Women: 1500 meter time below 2:10:00 minutes;

4. Men: 1500 meter time below 02:05:00 minutes.
These times should have been skated within a period of two months prior to study measurement;

5. Able to undergo reproducible lung function tests. Three-fold repetition of FEV1 measurements, with a mutual difference of maximal 5 percent (Miller, et al, 2005).

Exclusion criteria

1. Ultrasonic nebulization with tap water or saline solutions within 48 hours before testing;

2. FEV1 <70%;

3. Respiratory infection within 6 weeks prior to examination for which medication should be prescribed;

4. Use of short acting beta agonists 8 hours before exercise;

5. Use of long acting beta agonists 24 hours before exercise;

6. Use of a leukotriene-receptor-antagonist 36 hours before exercise.

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):	11-10-2012
Enrollment:	41
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2012
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	NL3407
NTR-old	NTR3550
Other	Sportmedisch Expertisecentrum, Tjongerschans Heerenveen : 12 001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A