The effect of nebulsied salbutamol and isotonic saline on exercise induced bronchoconstriction in elite skaters following a 1500 m race.

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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).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON37214

Source
ToetsingOnline

Brief title
OMRON and elite skaters

Condition

- Bronchial disorders (excl neoplasms)

Synonym
exercise induced asthma, Exercise inudeced airway obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Heerenveen Ziekenhuis, De Tjongerschans
Source(s) of monetary or material Support: Sportmedisch expertise centrum

Tjongerschans

Intervention

Keyword: Cold air, Elite athletes, Exercise provocation challenge

Outcome measures

Primary outcome

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

Secondary outcome

-Analyze the change in exercise induced increase of airway resistance, measured with the FOT, after five minutes of treatment with salbutamol, 0.9% NaCl and controls.

-Analyze the change in exercise induced decrease of airway reactance, measured with the FOT, after five minutes of treatment with salbutamol, 0.9% NaCl and controls.

-Analyzing the change in the electro physiological activity of the respiratory muscle system, measured with EMG after five minutes of treatment with Salbutamol ,isotonic saline and controls.

Study description

Background summary

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).

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).

Study design

Double blind, randomized, placebo-controlled design.

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.

Study burden and risks

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.

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

Age between 18 and 35 years.;Elite speedskater.;Women: 1500 meter time below 2:10:00 minutes.
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.;Able to undergo reproducible lung function tests. Three-fold repetition of FEV1 measurements, with a mutual difference of maximal 5 percent.

Exclusion criteria

Ultrasonic nebulization with Isotonic saline or tap water within 48 hours before testing.;FEV1 <70%.;Respiratory infection within 6 weeks prior to examination for which medication should be prescribed.;Use of short acting beta agonists 8 hours before testing.;Use of long acting beta agonists 24 hours before testing.;Use of leukotrineantagonists 36 hours before testing.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2012
Enrollment:	41
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Albutarol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-08-2012
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	29-10-2012
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
EudraCT	EUCTR2012-003600-12-NL
ClinicalTrials.gov	NCT3550
CCMO	NL41709.099.12