

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

Published: 23-08-2012

Last updated: 26-04-2024

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).

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

## Summary

### ID

NL-OMON37214

### Source

ToetsingOnline

### Brief title

OMRON and elite skaters

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

exercise induced asthma, Exercise induced airway obstruction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Heerenveen Ziekenhuis, De Tjongerschans

**Source(s) of monetary or material Support:** Sportmedisch expertise centrum

## 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**

### **Public**

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### **Scientific**

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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 leukotriene antagonists 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

EudraCT

ClinicalTrials.gov

CCMO

### ID

EUCTR2012-003600-12-NL

NCT3550

NL41709.099.12