# Effect of a single high dose of inhaled steroid on exercise induced laryngeal narrowing and bronchial asthma in children aged 12 - 17 years

Submission date	Recruitment status	Prospectively registered
08/10/2009	No longer recruiting	[] Protocol
Registration date	Overall study status	Statistical analysis plan
08/12/2009	Completed	[_] Results
Last Edited	Condition category	Individual participant data
08/12/2009	Respiratory	[] Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

### Contact information

Type(s) Scientific

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers IJsbaan 1-003

## Study information

#### Scientific Title

Single high dose of inhaled steroid on exercise induced laryngeal narrowing and bronchial asthma in children: a double-blind randomised cross-over placebo controlled trial

#### Acronym

IJsbaan-studie

#### **Study objectives**

Exercise-induced asthma can be reduced with a single high dose of corticosteroids. There is however a large variety of response within patient groups. In clinical practice children report a wheeze, and inspiratory stridor, a sign of extra-thoracic airway obstruction. With the use of full flow-volume loops an analysis can be made of intrathoracic (forced expiratory volume in one second [FEV1]) and extra-thoracic (mid-inspiratory flow [MIF50]) airway obstruction. The forced oscillation technique can be used to accurately evaluate reactance and resistance of intrathoracic airways.

The aim of this study was to evaluate the effect of a single high dose of fluticasone propionate with the expiratory flow loop and the forced oscillation technique, and evaluate the drop in MIF50 after exercise.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The local medical ethics committee (Medisch Etidsche Toetsingcommissie [METC]) Medisch Spectrum Twente (MST) Enschede approved on the 11th January 2005 (ref: P04-017). Date of ABR signing: 27th April 2004, Version: Juli 2002.

#### Study design

Double-blind randomised cross-over placebo-controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

#### Exercise induced asthma

#### Interventions

Four hours after inhalation of a single dose of either placebo or 1 mg fluticasone propionate children will perform an exercise challenge in cold, dry air. After 6 - 14 days children will cross-over in medication and will perform another exercise provocation challenge.

#### Intervention Type

Drug

**Phase** Phase III

#### Drug/device/biological/vaccine name(s)

Fluticasone propionate

#### Primary outcome measure

The difference in drop of FEV1 after exercise between fluticasone propionate and placebo, measured before and 1, 3, 6, 8, 12, 15, 20, 25 and 30 minutes after exercise.

All measurements were repeated 10 minutes after administration of 200 µg of salbutamol (a reliever drug).

#### Secondary outcome measures

1. The change in increase of resistance after exercise between fluticasone propionate and placebo, measured before and at 5, 14 and 24 minutes after exercise

2. The change in decrease of reactance after exercise between fluticasone propionate and placebo, measured before and at 5, 14 and 24 minutes after exercise

3. The drop in MIF50 after exercise, measured before and 1, 3, 6, 8, 12, 15, 20, 25 and 30 minutes after exercise

All measurements were repeated 10 minutes after administration of 200 µg of salbutamol (a reliever drug).

# Overall study start date 01/02/2005

**Completion date** 

01/04/2005

# Eligibility

#### Key inclusion criteria

- 1. Clinical history of airway obstruction after exercise
- 2. A drop of FEV1 of at least 10% after exercise
- 3. Aged between 12 and 17 years, either sex

4. Ability to perform reproducible lung function tests, i.e., coefficient of the predicted value variation in three of five consecutive measurements less than 5%

5. FEV1 greater than 70% of predicted value

6. Clinically stable period of at least 3 weeks before the study period

### Participant type(s)

Patient

#### Age group

Child

**Lower age limit** 12 Years

#### Upper age limit

17 Years

**Sex** Both

**Target number of participants** 23

#### Key exclusion criteria

1. Use of inhaled, intranasal or systemic corticosteroids in the last 4 weeks prior to the study 2. Use of anti-histamines, leucotrienes receptor antagonists, cromoglycates, anticholinergics and long acting bronchodilators in two weeks prior to the study

3. Other pulmonary or cardiac disorder

4. Deviation of more than 12% from baseline spirometry at a subsequent exercise challenge

### Date of first enrolment

01/02/2005

# Date of final enrolment 01/04/2005

### Locations

**Countries of recruitment** Netherlands

**Study participating centre Haaksbergerstraat 55** Enschede Netherlands 7513 ER

## Sponsor information

Organisation

Paediatric Research Foundation Enschede, Medical Centre Twente (Netherlands)

Sponsor details Haaksbergerstraat 55 VKC poli 17 Enschede Netherlands 7513 ER +31 (0)53 487 2310 kindergeneeskunde@ziekenhuis-mst.nl

**Sponsor type** Research organisation

Website http://www.mst.nl

ROR https://ror.org/033xvax87

## Funder(s)

**Funder type** Research organisation

**Funder Name** Paediatric Research Foundation Enschede, Medical Centre Twente (Netherlands)

### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### **IPD sharing plan summary** Not provided at time of registration