

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 08/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/12/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 08/12/2009	Condition category Respiratory	☐ Individual participant data ☐ 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

Protocol serial number
IJsbahn 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 intra-thoracic 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.

Primary study design

Interventional

Study design

Double-blind randomised cross-over placebo-controlled trial

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 Years

Upper age limit

17 Years

Sex

All

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)

ROR

<https://ror.org/033xvax87>

Funder(s)**Funder type**

Research organisation

Funder Name

Paediatric Research Foundation Enschede, Medical Centre Twente (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration