ISRCTN61380683 https://doi.org/10.1186/ISRCTN61380683

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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/12/2009	**Overall study status** Completed	
Last Edited 08/12/2009	**Condition category** Respiratory	

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 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.

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
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Sponsor information

Organisation

Paediatric Research Foundation Enschede, Medical Centre Twente (Netherlands)

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Sponsor type
Research organisation

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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