ISRCTN90761040 https://doi.org/10.1186/ISRCTN90761040

The protective effect of a nasal corticosteroid (Avamys®) on exercise induced airway obstruction in cold air in children

Submission date 09/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 03/07/2009	**Overall study status** Completed	
Last Edited 03/07/2009	**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

Protocol serial number
FF1, NL26953.044.09

Study information

Scientific Title

The protective effect of a nasal corticosteroid (Avamys®) on exercise induced airway obstruction in cold air in children: a randomised double-blind placebo-controlled single-centre trial

Acronym
YSCO

Study objectives
Three weeks of treatment with fluticasone furoate (Avamys®) in children will reduce exercise induced fall in forced expiratory volume in one second (FEV1) and maximum inspiratory flow rate at 50% of vital capacity (MIF50).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Review Committee (METC), Medical Centre Twente (Medisch Spectrum Twente), Enschede, approval pending as of 03/07/2009.

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled single-centre trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Allergic rhinitis and exercise induced asthma in children

Interventions
Three weeks +/- 5 days of treatment with fluticasone furoate (Avamys®) or placebo. Avamys® will be administered through a nasal spray, once daily, 27.5 µg in each nostril. In the first week of the study there will be a double dosing.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluticasone furoate (Avamys®)

Primary outcome(s)
1. Analyse the reduction in exercise induced fall of FEV1 after three weeks of treatment with fluticasone furoate
2. Analyse the reduction in exercise induced fall of MIF50 after three weeks of treatment with fluticasone furoate

Key secondary outcome(s)
1. To analyse the reduction in exercise induced increase of airway resistance, measured with the forced oscillation technique (FOT), after three weeks of treatment with fluticasone furoate
2. To analyse the reduction in exercise induced decrease of airway reactance, measured with the forced oscillation technique (FOT), after three weeks of treatment with fluticasone furoate
3. Analyze the reduction in fractional exhaled nitric oxide (FeNO), measured with miniNIOX® after three weeks of treatment with fluticasone furoate
4. To analyse the increase in quality of life, measured with the Paediatric Asthma Quality of Life Questionnaire (PAQLQ), after three weeks of treatment with fluticasone furoate
5. To analyse the increase in control of asthma, measured with the Asthma Control Questionnaire (ACQ), after three weeks of treatment with fluticasone furoate

Completion date
05/04/2009

Eligibility

Key inclusion criteria
1. Both males and females, aged between 12 and 17 years
2. Clinical history of allergic rhinitis and/or allergic asthma
3. Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in three of five consecutive measurements less than 5%
4. Maximal FEV1 greater than 70% of predicted value
5. Clinically stable period at least three 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 intranasal or systemic corticosteroids in the last four weeks prior to the study
2. Use of antihistamines, cromoglycates, anticholinergics in two weeks prior to the study
3. Use of long acting bronchodilators 24 hours before testing
4. Use of short acting bronchodilators eight hours before testing
5. Use of systemic corticosteroids, antihistamines, cromoglycates, anticholinergics, during the

study
6. Other pulmonary or cardiac disorder
7. Deviation of the FEV1 of more than 12% from baseline spirometry and the FEV1 before subsequent exercise provocation challenges
8. Signs of gastro-oesophageal reflux

Date of first enrolment
05/03/2009

Date of final enrolment
05/04/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Ariensplein 1
Enschede
Netherlands
75 11 JX

Sponsor information

Organisation
Paediatric Research Foundation Enschede, Medical Centre Twente (Netherlands)

ROR
https://ror.org/033xvax87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Paediatric Research Foundation Enschede, Medical Centre Twente (Stichting Pediatrisch Onderzoek Enschede, Medisch Spectrum Twente) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration