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Effects of waterfall aerosol on paediatric allergic asthma

Submission date	Recruitment status	[_] Prospectively registered
28/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2022	Respiratory	

Plain English summary of protocol

Background and study aims
Allergic asthma is the most common type of asthma, affecting both children and adults. It is correlated with allergies in about 90 % of children and about 50 % of adults. It is a complex disease with a strong genetic component, and it is characterized by recurrent episodes of wheezing, variable airway obstruction and bronchial hyper-reactivity (BHR).
Based on historical tradition and on observations, it has been suggested that waterfall aerosols may help fight paediatric allergic asthma. So far, this question has not been investigated and this is the aim of this study.

Who can participate?
Male/female children aged 8-15 years with mild to moderate persistent asthma according to GINA guidelines. Minimum medication to achieve adequate asthma control with inhaled corticosteroids and beta-sympathomimetics on demand.

What does the study involve?
Asthmatic allergic children will spend three weeks in an alpine asthma camp in the summer months of July and August in the village of Krimml (Austria). Half of the group will be exposed to the Krimml waterfall for one hour per day, whereas the other half will spend the same time at a control site without waterfall exposure. A number of tests will be carried out.

What are the possible benefits and risks of participating?
Benefits include improvements due to well described health effects of high altitude on asthma. The risks for the patients are comparable to a three weeks summer holiday in the Alps.

Where is the study run from?
The lead centre is the Laboratory of Translational Immuno-research of the Paracelsus Medical University Salzburg in cooperation with local medical doctors in the region of Salzburg/Pinzgau (Austria).

When is the study starting and how long is it expected to run for?
The study ran between July 2007 and December 2008.

Who is funding the study?
The study is funded by the Oesterreichische Forschungsfoerderungsgesellschaft (FFG) and the state province of Salzburg (Austria).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
415-E786/4-2007

Study information

Scientific Title
Effects of waterfall aerosol on paediatric allergic asthma: a randomized controlled trial

Study objectives
Does ionized waterfall aerosol have an effect on clinical, functional and immunological parameters of pediatric allergic asthma?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Comission, Salzburg [Ethikkommission für das Bundesland Salzburg], 3 December 2007, ref: 415-E786/4-2007

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Asthma bronchiole

Interventions
Intervention: Climate therapy (Asthma Camp in the Alps) at the site of a waterfall 1 hour in the day
Control: Climate therapy (Asthma Camp in the Alps) not at the site of a waterfall 1 hour in the day

Total duration: 3 weeks Asthma Camp

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Symptome score - Asthma control test (ACT) at day 1,11,19,50,80,140
2. Lung function (spirometry at day 0,3,7,9,11,13,15,17,19,20,80)
3. Exhaled nitrix oxide (NO) (FeNO) at day 0,10,14,18,20,80

Secondary outcome measures
Immunological parameters of allergic inflammation (blood collection at day 1, 20)

Overall study start date
01/01/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Male/female children aged 8-15 years with mild to moderate persistent asthma according to Global Initiative on Asthma (GINA) guidelines
2. Minimum medication to achieve adequate asthma control with inhaled corticosteroids and beta-sympathomimetics on demand

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
60

Total final enrolment
54

Key exclusion criteria
1. Systemic corticosteroids
2. Severe uncontrolled asthma

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Austria

Bosnia and Herzegovina

Germany

Study participating centre
Billrothstr. 11
Salzburg
Austria
5020

Sponsor information

Organisation
Austrian Research Promotion Agency [Österreichische Forschungsförderungsgesellschaft mbH (FFG)] (Austria)

Sponsor details
Sensengasse 1
Wien
Austria
1090

Sponsor type
Research organisation

Website
http://www.ffg.at

ROR
https://ror.org/028jc0449

Funder(s)

Funder type
Research organisation

Funder Name
Austrian Research Promotion Agency [Österreichische Forschungsförderungsgesellschaft mbH (FFG)] (Austria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2012	14/04/2022	Yes	No