

Effects of waterfall aerosol on paediatric allergic asthma

Submission date 28/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/04/2022	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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?

Dr Arnulf Hartl

arnulf.hartl@pmu.ac.at

Contact information

Type(s)

Scientific

Contact name

Dr Arnulf Hartl

Contact details

Billrothstr. 11

Salzburg

Austria

5020

+43 69 9144 20022

arnulf.hartl@pmu.ac.at

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 Commission, 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 bronchiol

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