

# Effects of waterfall aerosol on paediatric allergic asthma

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

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Arnulf Hartl

### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Asthma bronchiolite

**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(s)**

1. Symptom 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 nitric oxide (NO) (FeNO) at day 0,10,14,18,20,80

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

8 years

**Upper age limit**

15 years

**Sex**

All

**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)

**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

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/10/2012   | 14/04/2022 | Yes            | No              |