

Effects of winter exercise and the healing climate of caves on people with allergies and asthma

Submission date 25/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/03/2023	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The prevalence of allergic rhinitis (hay fever) and asthma has increased during the last decades. Therefore, allergies have become an enormous economic burden. Allergic diseases influence the quality of life of patients negatively, and in particular quality of sleep is impaired, which is leading to daytime sleepiness, reduced work productivity and worse school performance. The conservative treatment of allergic includes several drugs like antihistamines, bronchodilators and glucocorticoids. Next to this, travels to and/or stays at high altitude have a long tradition in the therapy of asthma and have been described to have positive long-term effects. Another natural treatment method for allergies and asthma is the so-called speleotherapy. Speleotherapy uses the specific microclimate of old mines and caves to treat respiratory diseases. Although, physicians very often recommend regular exercise for patients with allergies and asthma, scientific evidence and evidence-based guidelines are lacking about recreational winter exercise. The aim of this study is to assess the effects of winter exercise and of speleotherapy in combination with winter exercise on patients with allergies and asthma.

Who can participate?

Men and women aged 18-55 with a house dust mite allergy and controlled allergic rhinitis and/or allergic asthma, and moderate skiing skills to meet the demands of the winter exercise program.

What does the study involve?

Participants are randomly allocated into three groups: a control group and two intervention groups (speleo- and exercise group). The intervention groups spent a 10-day winter holiday in the holiday region National Park Hohe Tauern (Austria). The exercise group participated in a whole-day winter sports program and the speleo group spent 1.5 hours every day in a mine and participated in half-day winter sports program. Medical examinations (lung function, blood tests, endurance etc) are performed at the beginning of the study, after the 10-day holiday and after 2 months.

What are the possible benefits and risks of participating?

The direct benefit for the participants is a ten-day winter holiday with exercise and/or speleo

therapy. A vacation improves mood and quality of life. As a negative side effect of physical activity, exercise-induced bronchoconstriction (constriction of the airways) may occur.

Where is the study run from?

The Paracelsus Medical University of Salzburg performed this study. All medical examinations were performed by members of the Institute of Ecomedicine from the Paracelsus Medical University of Salzburg. The speleo and exercise program took place in region National Park Hohe Tauern (Austria), the control group receive no intervention and stay at home (Austria).

When is the study starting and how long is it expected to run for?

Intervention group with winter exercise and speleotherapy & control group: March-May 2013

Intervention group with winter exercise: December 2013- February 2014

Who is funding the study?

This research was funded by Lighthouse projects in tourism award 2011 "Year-round destination Hohe Tauern Health", Winner of the 1st price, Austrian Federal Ministry of Economic Affairs, Family and Youth

Who is the main contact?

Dr Arnulf Hartl

Study website

<http://www.tauernhealth.com/>

Contact information

Type(s)

Scientific

Contact name

Dr Arnulf Hartl

Contact details

Strubergasse 22

Salzburg

Austria

5020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

415-E/1553/2-2012

Study information

Scientific Title

Winter exercise and speleotherapy for allergy and asthma - the WESPAA study

Acronym

WESPAA

Study objectives

Winter exercise and winter exercise in combination with the healing climate of mines/caves (speleotherapy) improve allergic airway inflammation in adults suffering from allergic rhinitis and/or allergic asthma.

Winter exercise and winter exercise in combination the healing climate of mines/caves improve health related quality of life in adults suffering from allergic rhinitis and/or allergic asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Salzburg, Amt der Salzburger Landesregierung, Postfach 527, 5010 Salzburg, Tel: +43 (0)662 8042 2375, Email: ethikkommission@salzburg.gv.at, 15/11/2012, ref: E1987/5-2016

Study design

Randomized controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Allergy, asthma, respiratory allergies, house dust mite allergy

Interventions

The intervention groups spent a 10-day winter holiday in the Holiday region National Park Hohe Tauern (Austria). The exercise group participated in a whole-day winter sports program and the speleotherapy group spent every day 1.5h in a mine and participated in half-day winter sports program. The control group did not received any intervention.

Intervention Type

Mixed

Primary outcome measure

Measured at baseline (day 0), day 10 and day 60:

1. Allergic airway inflammation assessed using exhaled nitric oxide
2. Health related quality of life assessed using RhinAsthma Quality of Life Scale

Secondary outcome measures

Measured at baseline (day 0), day 10 and day 60:

1. Inflammation/allergic inflammation assessed using differential blood count
2. Cardiorespiratory fitness assessed using the 6-Minute Walk Test
3. Lung function assessed using spirometry
4. Allergic inflammation in the upper airways assessed using eosinophilic cell count from nasal lavage
5. Cleaning rate of the upper airways assessed using mucociliary clearance (saccharin test)
6. Allergic symptoms and health status assessed using the Visual Analogue Scale
7. Chronic stress level assessed using the Trier Inventory for chronic stress (TICS)
8. General health/health-related quality of life assessed using SF-36
9. Asthma control status assessed using Asthma Control Test
10. Health related quality of life for asthma assessed using Asthma Quality of Life Questionnaire
11. Disease-specific health related quality of life assessed using Sinonasale Outcome Test

Overall study start date

01/10/2012

Completion date

28/02/2014

Eligibility

Key inclusion criteria

1. Age between 18-55 years
2. House dust mite sensitization (RAST > 2; positive PRICK-Test or total IgE > 0.7 kU/l)
3. Controlled allergic rhinitis and/or allergic asthma
4. Physical ability, including moderate skiing skills, to meet the demands of the exercise program

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

90

Key exclusion criteria

1. Uncontrolled asthma (Asthma Control Test < 20)
2. Malignant neoplastic disorders
3. Exercise induced bronchoconstriction
4. Cardiovascular diseases
5. Orthopedic diseases
6. Lung function disorder
7. Acute infection or fever
8. Uncontrolled metabolic diseases
9. Pregnancy

Date of first enrolment

19/11/2012

Date of final enrolment

15/02/2013

Locations**Countries of recruitment**

Austria

Germany

Study participating centre

Paracelsus Medical University Salzburg

Institute of Ecomedicine

Strubergasse 22

Salzburg

Austria

5020

Sponsor information**Organisation**

Paracelsus Medical University

Sponsor details

Research Office

Strubergasse 21

Salzburg
Austria
5020

Sponsor type

University/education

Website

<https://www.pmu.ac.at/>

ROR

<https://ror.org/03z3mg085>

Funder(s)

Funder type

Government

Funder Name

Austrian Federal Ministry of Economic Affairs, Family and Youth

Results and Publications

Publication and dissemination plan

Study protocol is not published yet – as the protocol is only available in German, it will not be shared. One publication will focus on the effects of winter exercise on people with allergies and asthma and a second publication will focus on the combined effects of speleotherapy and winter exercise.

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Arnulf Hartl (arnulf.hartl@pmu.ac.at). Data will be shared after publication; data will be shared for meta-analysis, data will be shared upon request via e-mail; data will be shared only for research purpose; consent from participants was obtained; no ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Subsection of data	08/06/2019	22/03/2023	Yes	No

