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Effects of acute hydroxy gas inhalation on exercise-induced bronchoconstriction

Submission date
17/10/2023

Recruitment status
No longer recruiting

Registration date
24/10/2023

Overall study status
Completed

Last Edited
20/11/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Exercise-induced bronchoconstriction (EIB) is a common obstructive airway disease within athletic populations. Treatments that can control EIB and reduce inflammation without side effects are beneficial. Previous research into hydrogen gas has demonstrated a reduction of inflammation across a range of diseases. Given the administering route of inhalation, this makes it a potentially favourable treatment in the management of asthma and EIB. The effect of hydrogen gas on asthma has received attention, but the effect remains unclear. The aim of this study is to assess markers of airway inflammation and lung function in those with objective evidence of exercise-induced bronchoconstriction.

Who can participate?
Adult patients with EIB aged 18 to 50 years old

What does the study involve?
Participants will be asked to inhale either hydroxy gas (2-3% hydrogen gas) or placebo gas (control condition) for 60 minutes using a nasal cannula before a bronchoprovocation test, followed by a further 30-minute inhalation. Lung function, urine and blood samples will be taken before and after each test to measure airway inflammation and lung function.

What are the possible benefits and risks of participating?
Participants will receive a lung function report which will inform them of their current asthma management. To date there are no known side effects to hydroxy gas inhalation, however, this will be continually monitored throughout the research study.

Where is the study run from?
University of Kent (UK)

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
Osmio Water Technology (UK)

Who is the main contact?
Miss Savannah Sturridge, sas92@kent.ac.uk (UK)

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Miss Savannah Sturridge

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effects of acute hydroxy gas inhalation on lung function and inflammatory markers in individuals with mild to moderate asthma and exercise-induced bronchoconstriction (EIB)

Acronym
EIB

Study objectives

In individuals with exercise-induced bronchoconstriction (EIB), lung function and airway inflammation will be improved when using hydroxy gas in combination with prescribed medication compared to prescribed medication alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/12/2021, School of Sport & Exercise Sciences Research Ethics and Advisory Group (REAG) (University of Kent, School of Sport and Exercise Sciences, Chipperfield Building, Canterbury, CT2 7PE, United Kingdom; -; ssesethics@kent.ac.uk), ref: 24_20_21

Study design
Single-centre randomized crossover double-blind study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Other

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
Exercise-induced bronchoconstriction

Interventions
There are 4 study visits.

Each participant will inhale either hydroxy gas (2-3% hydrogen gas) or placebo gas (control condition) for 60 minutes using a nasal cannula before a bronchoprovocation test, followed by a further 30-minute inhalation. The order will be randomised using computer randomisation software and neither the researcher nor the participant will know which gas is being inhaled until the completion of the study. Lung function, urine and blood samples will be taken before and after each test to measure airway inflammation and lung function.

The bronchoprovocation test
A Eucapnic Voluntary Hyperpnoea (EVH) Challenge is a bronchoprovocation test used as a surrogate for exercise to objectively identify exercise-induced bronchoconstriction (EIB). The EVH challenge involves the inhalation of cold, dry air (gas mixture of 21% oxygen, 5% carbon dioxide, and balance nitrogen) for 6 minutes at a high ventilation rate that will induce bronchoconstriction in those with EIB. At baseline, lung function will be measured in triplicate

using spirometry and following the EVH challenge at 3, 5, 7, 10 and 15 minutes in duplicate. If a fall from baseline in forced expiratory volume in one second (FEV1) of 10% or more is demonstrated, a bronchodilator will be administered to reverse the drop in lung function. The EVH challenge will be performed at each visit in this research study to demonstrate the effects if any, of the inhalation of hydroxy gas prior to the EVH challenge on lung function fall in those with EIB and markers of airway inflammation within the blood samples.

The principle investigator is the intervention provider and has a gas safety training certificate to perform the bronchoprovocation test (EVH challenge) and use the hydroxy gas machine. All research testing will be conducted face-to-face with each participant individually. The research will take place within the University physiology laboratory with gas safety monitors.

Intervention Type
Other

Primary outcome measure
1. Eucapnic Voluntary Hyperpnoea (EVH) challenge with lung function measures taken in triplicate before and in duplicate at 3, 5, 7, 10 and 15 minutes post EVH challenge.
2. Urinary 9α,11β-prostaglandin and Clara cell protein (CC16) levels measured using enzyme-linked immunosorbent assay (ELISA) of samples collected before and after (~1 h) EVH challenge
3. Blood hydroxyl radical levels measured using a blood test in samples before and after (~1 h) EVH challenge

Secondary outcome measures
Difficulty breathing measured using the revised Borg Rating of Perceived Exertion (RPE) scale at baseline and immediately following the EVH challenge

Overall study start date
20/09/2021

Completion date
03/06/2024

Eligibility

Key inclusion criteria
1. Ability to consent to the research
2. Aged 18 to 50 years old
3. Current clinical-based diagnosis of exercise-induced bronchoconstriction
4. Normal resting forced expiratory volume in one second (FEV1) defined as greater than 80% predicted value

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Chest infection within the past 4 weeks or hospitalisation
2. Baseline FEV1 <80% predicted value
3. Any other respiratory condition (other than asthma)
4. Any other chronic medical conditions (e.g., cardiovascular, neurological and metabolic)

Date of first enrolment
03/01/2022

Date of final enrolment
08/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Kent
School of Sport and Exercise Sciences
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Sponsor information

Organisation
University of Kent

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Sponsor type
University/education

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ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Industry

Funder Name
Osmio Water Technology

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
02/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Savannah Sturridge (sas92@kent.ac.uk) after the completion and publication of study results (de-identified participant data).

IPD sharing plan summary
Available on request