

Effects of acute hydroxy gas inhalation on exercise-induced bronchoconstriction

Submission date 17/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/11/2023	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

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

ORCID ID

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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; -; ssethics@kent.ac.uk), ref: 24_20_21

Study design

Single-centre randomized crossover double-blind study

Primary study design

Interventional

Study type(s)

Other

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(s)

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 9 α ,11 β -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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Kent

School of Sport and Exercise Sciences

Chipperfield Building

Canterbury

United Kingdom

CT2 7PE

Sponsor information

Organisation

University of Kent

ROR

<https://ror.org/00xkeyj56>

Funder(s)

Funder type

Industry

Funder Name

Osmio Water Technology

Results and Publications

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

