ISRCTN11644788 https://doi.org/10.1186/ISRCTN11644788

# 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**
08/07/2026

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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?
Dr Savannah Sturridge, Savannah.Sturridge@brunel.ac.uk (UK)

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Savannah Sturridge

### ORCID ID
https://orcid.org/0009-0006-9475-8251

### Contact details
University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
Canterbury
United Kingdom
CT2 7PE
None available
Savannah.Sturridge@brunel.ac.uk

# Additional identifiers

# 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

### Primary study design

Interventional

## Study design
Single-centre randomized crossover double-blind study

## 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 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

## 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

### Total final enrolment
0

### 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
England
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 (Savannah.Sturridge@brunel.ac.uk) after the completion and publication of study results (de-identified participant data).

### IPD sharing plan summary
Available on request