The effects of hydrogen-rich water on exercise performance and lung function

Submission date	Recruitment status	Prospectively registered
23/10/2023	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
26/10/2023	Completed	Results
Last Edited	Condition category	Individual participant data
20/11/2023	Respiratory	Record updated in last year

Plain English summary of protocol

Background and study aims

Research into hydrogen-rich water has demonstrated some positive effects across a number of diseases and sports performance. To date, no research has investigated the effects on physically active asthmatics whereby the benefits might be twofold (improving asthma severity and exercise performance). The aim of this study was to investigate whether short- and long-term hydrogen-rich water can improve cycling performance and lung function in physically active asthmatics and healthy physically active males compared to plain water.

Who can participate?

Healthy physically active males and those with asthma aged between 18 to 55 years old

What does the study involve?

All participants will drink hydrogen-rich water and plain water for 2 weeks each in a randomised order. Physiological measures taken will include VO2 max test, finger-tip blood lactate samples, venous blood samples of airway inflammatory markers, breath-by-breath gas analysis, and near-infrared spectroscopy for tissue oxygen saturation and lung function using spirometry. Exercise performance measures taken will include time to complete a 5km cycling time trial.

What are the possible benefits and risks of participating?

Participants will receive a VO2 max report which gives an indication of current fitness level. Lung function reports will be able to inform participants of current asthma management. To date, there are no known side effects of hydrogen-rich water which 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? June 2023 to June 2024

Who is funding the study?

- 1. Osmio Water Technology (UK)
- 2. University of Kent (UK)

Who is the main contact? 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The acute and chronic ingestion of hydrogen-rich water on 5km time trial performance and lung function in physically active individuals

Study objectives

The acute and chronic ingestion of hydrogen-rich water will lead to a faster 5km cycling time trial in addition to improving lung function and reduce inflammatory markers in physically active males with exercise-induced bronchoconstriction (EIB) compared to plain water.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/05/2023, University of Kent, School of Sport & Exercise Sciences, Research Ethics and Advisory Group (Chipperfield Building, Canterbury, Ct2 7PE, United Kingdom; None available; ssesethics@kent.ac.uk), ref: 27_20_23

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

In total, participants will visit on 6 occasions which include the following visits:

Visit 1 - Confirmation of group (indirect bronchoprovocation test - see below for further detail)

Visit 2 - VO2 max test on a cycle ergometer

Visit 3 - Acute (following a single 1L of randomly assigned first water condition)

Visit 4 - Chronic (following 2 weeks of 1L a day of the randomly assigned first water condition)

Visit 5 - Acute (following a single 1L of randomly assigned second water condition)

Visit 6 - Chronic (following 2 weeks of 1L a day of the randomly assigned second water condition)

Participants will be allocated into a 'healthy' group or the exercise-induced bronchoconstriction (EIB) group using an indirect airway bronchoprovocation challenge (eucapnic voluntary hyperpnoea (EVH) challenge). The EVH challenge is a 6-minute inhalation of a gas mixture containing 21% oxygen, 5% carbon dioxide and balance nitrogen at a high minute ventilation. In participants with EIB, lung function will significantly reduce (10% or more) following an EVH challenge compared to healthy volunteers. On the following visit, participants will complete a VO2 max test which assesses their current fitness level. Then, participants will be instructed to

drink 1 litre a day of either hydrogen-rich water or plain water for 2 weeks. There will be a 1-week washout period then the following 2 weeks they will be instructed to drink the alternative drinking water. The order of drinking water will be randomised using computer randomisation software. At each visit, a 5km time trial will be completed including lung function at baseline. To assess the chronic effect of hydrogen-rich water on airway inflammation, blood samples will be taken within 2 weeks of each condition.

Intervention Type

Supplement

Primary outcome measure

- 1. Exercise performance measured using one 5km cycling time trial assessed by completion time. This will be done following a single 1L of the drink (acute) and following 2 weeks of drinking 1L a day of the drink (chronic).
- 2. Urine levels of $9a,11\beta$ -prostaglandin and Clara cell protein (CC16) measured in venous blood samples collected at the end of the two weeks of each water condition using enzyme-linked immunosorbent assay (ELISA) method at baseline of that final visit.

Secondary outcome measures

To determine whether hydrogen-rich water improves exercise performance and/or the physiological response to exercise, the following measures will be taken:

- 1. Gas exchange (VO2, VCO2) measured using a respiratory gas analyser at each 1km of the 5km time trials
- 2. Perceptual responses measured using the Borg Rating of Perceived Exertion (RPE) scale at each 1km of the 5km time trials
- 3. Heart rate measured using a heart rate Bluetooth chest band at each 1km of the 5km time trial
- 4. Blood lactate concentration measured using finger prick blood samples before and after each 5km time trial

To determine whether hydrogen-rich water improves lung function, the following outcome variable will be assessed:

Lung function measured using spirometry following participants drinking 1 litre of water and following 2 weeks (1 litre of water a day)

Overall study start date

06/03/2023

Completion date

03/06/2024

Eligibility

Key inclusion criteria

- 1. Ability to consent to the research
- 2. Aged 18 to 55 years old
- 3. Physically active (defined as engaging in at least 75 minutes of high intensity exercise a week)
- 4. Either a diagnosis of Exercise-Induced Bronchoconstriction or without a diagnosis
- 5. Normal resting Forced Expiratory Volume in One Second (FEV1) defined as >80% predicted value.

Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Male

Target number of participants

Two groups which includes a total of 10 'healthy' participants and 10 participants with Exercise-Induced Bronchoconstriction (EIB)

Key exclusion criteria

- 1. Respiratory infection or hospitalisation related to respiratory conditions in the last 4 weeks
- 2. Respiratory condition other than an asthma-related condition
- 3. Chronic medical conditions (e.g., metabolic, neurological, cardiovascular etc)

Date of first enrolment

29/05/2023

Date of final enrolment

06/05/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Kent

The Registry Canterbury United Kingdom CT2 7NZ

Sponsor information

Organisation

University of Kent

Sponsor details

Research and Information Services
The Registry
Canterbury
England
United Kingdom
CT2 7NZ
None available
researchculture@kent.ac.uk

Sponsor type

University/education

Website

http://www.kent.ac.uk/

ROR

https://ror.org/00xkeyj56

Funder(s)

Funder type

University/education

Funder Name

University of Kent

Alternative Name(s)

The University of Kent

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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

IPD sharing plan summary

Available on request