

The acute effects of hydroxy gas on people with Parkinson's disease

| | | |
|----------------------------------------|------------------------------------------------------|--------------------------------------------------------------|
| Submission date 07/06/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 20/06/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 20/11/2023 | Condition category Nervous System Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years. The 3 main symptoms of Parkinson's disease are involuntary shaking of particular parts of the body (tremor), slow movement, stiff and inflexible muscles. There is no cure and no disease-modifying therapies available for Parkinson's disease (PD). As cases of PD are set to double in the next twenty years - primarily due to an aging population - it is important that therapeutic applications which aid in the reduction of PD symptoms are explored. There is an abundance of evidence to support hydrogen having beneficial effects in various diseases, however, this is usually consumed through drinking hydrogen rich water. To date there are only two studies which have investigated the effects of inhalation of hydrogen gas in people with Parkinson's (PwP) (as opposed to animal models), and both studies focussed on the chronic effects of hydrogen gas inhalation. This study would like to investigate if hydrogen gas inhalation over a two hour period of time impacts motor and non-motor symptoms of PD, and blood markers of inflammation/neuro-inflammation, and oxidative stress. The use of a repeated measure design (baseline, after one hour of gas inhalation, and after two hours of gas inhalation) will give an indication of what period of inhalation is optimal to reduce symptoms of PD, if hydrogen gas inhalation does impact PwP.

Who can participate?

People with Parkinson's

What does the study involve?

A hydroxy gas (2-4% hydrogen gas) or placebo gas will be inhaled for two hours by participants at two visits. This is a randomised, double-blind, crossover, placebo-controlled study – meaning the researcher and participant will not know which gas is being inhaled at each visit. There will be two test visits in total and at one visit a placebo or hydroxy gas is administered, and then the second visit, the gas which the participant has not already inhaled, will then be inhaled. The participant will be asked to sit for two hours inhaling the hydroxy gas or placebo gas in a room in the School of Sport and Exercise Sciences building at the University of Kent (Canterbury, UK). The participant will be able to have toilet breaks as and when needed. The study measures and timings are detailed below:

What are the possible benefits and risks of participating?

There is no direct benefit to taking part.

Hydrogen is safe to consume, and has shown no adverse effects in animals or humans and safety standards regarding high concentrations of hydrogen used in deep-diving gases to aid in prevention of sickness have long been established. We do not anticipate any adverse reaction to the hydrogen gas due to the previously shown safety.

Where is the study run from?

University of Kent (UK)

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

October 2021 to March 2023

Who is funding the study?

Osmio Water Technology (UK)

Who is the main contact?

Kimberly Dargan, kvd4@kent.ac.uk

Contact information

Type(s)

Public

Contact name

Mrs Kimberly Dargan

ORCID ID

<https://orcid.org/0000-0001-7444-5414>

Contact details

University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
Canterbury
United Kingdom
CT2 7PE
+44 1227 816945
kvd4@kent.ac.uk

Type(s)

Scientific

Contact name

Mrs Kimberly Dargan

Contact details

University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
Canterbury

United Kingdom
CT2 7PE
+44 1227 816945
kvd4@kent.ac.uk

Type(s)

Principal investigator

Contact name

Mrs Kimberly Dargan

Contact details

University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
Canterbury
United Kingdom
CT2 7PE
+44 1227 816945
kvd4@kent.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

UoK SSES REAG Ref No. 26_20_21

Study information

Scientific Title

The acute effects of hydroxy gas inhalation on motor and non-motor functions and blood biomarkers in people with Parkinson's

Study objectives

1. Inhalation of hydroxy gas lowers POMS Total Mood Disturbance score (indicative of a more stable mood profile) compared to inhalation of a placebo gas
2. Inhalation of hydroxy gas improves cognitive function compared to inhalation of a placebo gas
3. Inhalation of hydroxy gas improves dexterity compared to inhalation of a placebo gas
4. Inhalation of hydroxy gas reduces inflammation/neuro-inflammation compared to inhalation of a placebo gas
5. Inhalation of hydroxy gas reduces oxidative stress more than inhalation of a placebo gas

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/12/2021, University of Kent School of Sport and Exercise Sciences Research Ethics and Advisory Group (REAG) (SSES, University of Kent, Chipperfield Building, Kent, CT2 7PE, UK; no telephone number provided; ssesethics@kent.ac.uk), ref: 26_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

Parkinson's disease

Interventions

Each participant will inhale a hydroxy gas (2-3% hydrogen gas) or placebo gas (control condition) for two hours using a nasal cannula. The order of gas inhalation (hydroxy gas or placebo gas) will be randomised using computer randomisation software and neither the researchers nor participants will know which was which until after the study is complete. All participants will receive hydroxy gas and placebo gas. Mood state (measured by POMS), cognitive function (measured by a Flanker Compatibility Task), and dexterity (using a Purdue Pegboard Test) will be assessed and blood samples (to assess for markers of inflammation/neuro-inflammation and oxidative stress) will be taken at both visits at baseline, one hour of inhalation, and at two hours of inhalation.

Intervention Type

Supplement

Primary outcome(s)

Cognitive function and manual dexterity to be measured using a Purdue Pegboard Test (the three-trial administration test-retest will be used to increase reliability) at baseline, after 1 h of gas inhalation and after 2 h of gas inhalation.

Key secondary outcome(s)

All of the following measures will be assessed at time points of: baseline, after 1 h of gas inhalation, and after 2 h of gas inhalation:

1. Transient mood measured using a Profile of Mood States (POMS)– Short Form.
2. Visual attention measured using The Flanker Compatibility Task
3. Tremor measured using Part 3 of the Unified Parkinson's Disease Rating Scale
4. Blood markers of oxidative stress and of inflammation/neuro inflammation will be measured in serum or plasma derived from venous blood samples.

Completion date

10/03/2023

Eligibility

Key inclusion criteria

1. All participants must have a diagnosis of PD by a Neurologist or Geriatrician.
2. All participants must be at stage 2 or stage 3 on the Hoehn and Yahr (H&Y) scale. Stage 1 is too mild and stages 4 and 5 could potentially be too severe for appropriate study participation.
3. Male or female.
4. Able to attend the School of Sport and Exercise Sciences facilities and sit for a period of two hours.
5. All participants should be stable in the past two months.

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Participants whose Parkinson's is not controlled.
2. Participants who are at stage 1, stage 4 and stage 5 of the H&Y scale.
3. Participants who cannot consent for themselves.

Date of first enrolment

26/07/2022

Date of final enrolment

01/12/2022

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 Kimberly Dargan (kvd4@kent.ac.uk) after completion and publication of study results (de-identified participant data).

IPD sharing plan summary

Available on request