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

Submission date	Recruitment status	[X] Prospectively registered
07/06/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/06/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/11/2023	Nervous System Diseases	[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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
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 measure
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.

Secondary outcome measures
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 measured in serum or plasma derived from venous blood samples.

Overall study start date
01/10/2021

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

Age group
Adult

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre
University of Kent
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Sponsor information

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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 peer-reviewed journal.

Intention to publish date
10/09/2023

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