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The chronic effects of hydroxy gas on people with Parkinson’s disease - a case study

Submission date 05/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/05/2023	**Overall study status** Completed	
Last Edited 20/11/2023	**Condition category** Nervous System Diseases	

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 ageing 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). This study would like to investigate if hydrogen gas inhalation over a two-week period of time impacts motor and non-motor symptoms of PD, physical activity levels and blood markers of inflammation/neuro-inflammation, BDNF, and oxidative stress.

Who can participate?
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
5. Able to inhale gas for 30 minutes, twice daily for eight weeks
6. Participants' disease state must be stable over the past two months

What does the study involve?
Inhalation of hydrogen or placebo gas for a total of eight weeks. The first two weeks will be spent inhaling placebo gas, followed by two weeks of inhaling hydroxy gas, then two weeks of inhaling placebo gas, then a two week inhalation of hydroxy gas. Inhalation of the gas needs to be 30 minutes long, twice daily. The participant is required to wear an activity tracker for the full eight weeks.

Attending the School of Sport and Exercises Lab at baseline, two weeks, four weeks, six weeks and eight weeks (five visits in total), where the following measures will be taken:
1. 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)
2.Transient mood measured using a Profile of Mood States (POMS)– Short Form
3. Visual attention measured using The Flanker Compatibility Task
4. The burden of non-motor symptoms, including non-motor fluctuations, using the Movement Disorder Society Non-Motor Rating Scale
5. Blood markers of oxidative stress and of inflammation/neuro inflammation, and BDNF will measured in serum or plasma derived from venous blood samples

What are the possible benefits and risks of participating?
Benefits:
Will enable researchers to determine if hydrogen gas inhalation improves symptoms of Parkinson's disease
Risks:
Venous blood sampling
Venous blood will be taken in order to assess the participant for markers of inflammatory status and antioxidant capacity in the blood. It is possible the participant may suffer from bruising from the puncture site

Where is the study run from?
University of Kent, School of Sport and Exercise Sciences (UK)

When is the study starting and how long is it expected to run for?
November 2022 to March 2024

Who is funding the study?
Osmio Water Technology (UK)

Who is the main contact?
Kimberly Dargan, kvd4@kent.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
UoK SSES REAG Ref No. 21_20_23

Study information

Scientific Title
The chronic effects of hydroxy gas inhalation on motor and non-motor functions and blood biomarkers in people with Parkinson's - a case study

Study objectives
1. Inhalation of hydroxy gas lowers Profile of Mood States 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
6. Inhalation of hydroxy gas reduces sedentary time compared to inhalation of placebo gas
7. Inhalation of hydroxy gas increases BDNF

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2023, 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: 21_20_23

Primary study design
Interventional

Study design
Single-centre ABAB single-blind study

Study type(s)
Other

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
The study design is an ABAB design. 'A' is the placebo gas, 'B' is the hydroxy gas. Each arm will last for two weeks, the study will run for eight weeks in total. Each participant will inhale a hydroxy gas (2-3% hydrogen gas) or placebo gas (control condition) for 30 min, twice a day (once in the morning, and once in the evening) using a nasal cannula. 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 BDNF, markers of inflammation /neuro-inflammation, and oxidative stress), will be taken at baseline, after two weeks of inhalation, after four weeks of inhalation, after six weeks of inhalation, and after eight weeks of inhalation. An activity tracker will be worn continuously for eight weeks.

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 each visit (at baseline, after 2 weeks of placebo gas inhalation, after 2 weeks of hydroxy gas inhalation, after 2 weeks of placebo gas inhalation, after 2 weeks of hydroxy gas inhalation.

Key secondary outcome(s)
Measures 1-4 will be assessed at time points of: baseline, after 2 weeks of placebo gas inhalation, after 2 weeks of hydroxy gas inhalation, after 2 weeks of placebo gas inhalation, after 2 weeks of hydroxy 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. The burden of non-motor symptoms, including non-motor fluctuations, using the Movement Disorder Society Non-Motor Rating Scale
4. Blood markers of oxidative stress, inflammation/neuro inflammation, BDNF will measured in serum or plasma derived from venous blood samples
5. Levels of physical activity measured by an activity tracker worn continuously for eight weeks

Completion date
01/03/2024

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
5. Able to inhale gas for 30 min, twice daily, for a period of 8 weeks
6. Participants' disease state must be stable over the past 2 months

Participant type(s)
Patient

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
10/05/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
Canterbury
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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