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Tibial nerve stimulation to improve bladder symptoms in Parkinson's

Submission date
06/05/2021

Recruitment status
No longer recruiting

Registration date
22/06/2021

Overall study status
Completed

Last Edited
20/05/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Bladder symptoms are extremely common in Parkinson’s disease (PD) and have a profound impact on quality of life. Transcutaneous tibial nerve stimulation (TTNS) is a potential method of treating overactive bladder symptoms in neurological disorders. If effective, this will improve bladder symptoms in PD without side effects encountered with drugs and potentially prevent falls and hospital admission associated with urinary disorders.

Who can participate:
People with Parkinson's with bladder symptoms (not caused by any obvious structural problem)

What does the study involve:
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group of participants will be asked to use a small, self-adhesive stimulator device that affects the bladder, called Geko, on the lower leg, twice per week for 30 min at a time, over 12 weeks. The other group of participants will use the same device at a lower stimulation strength that does not affect the bladder. The treatment itself is given at home by the participant. Participants will be asked to rate their bladder symptom score with a questionnaire every other week, and more thorough bladder testing will be organised just before and just after the 12 week period at the Royal United Hospital in Bath (UK). This will require a visit to the research clinic, but the stimulation treatment is given at home by the participants themselves.

What are the possible benefits and risks of participating?
It is hoped that tibial nerve stimulation using the Geko device will improve bladder symptoms. It is hoped that the Geko device will be easy to use without any possible trip hazards of using other methods explored in the past such as TENS machines. The Geko device is already licensed in the UK for another purpose and the only main side effect can be some skin irritation (which is rare).

Where is the study run from?
The University of Bristol (UK)

When is the study starting and how long is it expected to run for?
From February 2021 to April 2024

Who is funding the study?
The Gatsby Charitable Foundation (UK)

Who is the main contact?
Dr Matthew Smith
matthew.smith@bristol.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295856

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 295856

Study information

Scientific Title

STRIPE (Stimulation of the Tibial nerve Repetitively to Improve Incontinence in Parkinson’s disease Electronically): A randomised controlled trial of tibial nerve stimulation to improve bladder symptoms in patients with idiopathic Parkinson’s disease

Acronym
STRIPE

Study objectives
Tibial nerve stimulation provided by a novel self-adhesive device will improve bladder symptoms in Parkinson's

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2021, London - Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre,
Holland Drive, Newcastle/London, NE2 4NQ, UK; +44 (0)207 104 8233; CamdenandKingsCross.REC@hra.nhs.uk), ref: 21/LO/0418, 21/NI/0091

Study design
Single-blinded randomized control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bladder symptoms in Parkinson's

Interventions
Tibial nerve stimulation using the Geko device, a self adhesive neuromuscular stimulator.
This will be compared to a placebo arm using this device, in a way that does not provide threshold nerve stimulation. Stimulation will be given twice per week for 30 min, for a period of 12 weeks. Participants will be randomised electronically using a minimisation technique.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Geko

Primary outcome(s)
Quality of life measured using the International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB) at baseline, 2, 4, 6, 8, 10, 12, 16, 20, and 24 weeks

Key secondary outcome(s))
1. Urinary frequency rate, incontinence episodes, and nocturia measured using a bladder diary at baseline and 12 weeks
2. Quality of life measured using the ICIQ-OABqol and the EuroQol 5-dimension (EQ5D) questionnaires at baseline and 12 weeks
3. Mood measured using the Patient Health Questionnaire-9 (PHQ9) at baseline and 12 weeks
4. Neurogenic bowel dysfunction measured using the Neurogenic bowel score at baseline and 12 weeks
5. Bladder function measured using uroflowmetry and post-void residual at baseline and 12 weeks
6. Autonomic function measured using Scales for Outcomes in Parkinson's Disease - Autonomic Dysfunction (SCOPA-AUT) questionnaire at baseline and 12 weeks
7. Device tolerability and adverse events measured using participant diaries between baseline and 12 weeks

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Idiopathic Parkinson's Disease
2. Ability to consent
3. Aged ≥18 years
4. Determined to have significant bladder symptoms as defined by questionnaire response within PRIME-Parkinson study or referred from non-PRIME centres at recommendation of local clinician due to bladder symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
18 years

Sex
All

Total final enrolment
148

Key exclusion criteria
1. Parkinsonism of any other aetiology such as but not limited to drug-induced Parkinsonism (DIP), multiple system atrophy (MSA), corticobasal degeneration (CBD), vascular parkinsonism,

and progressive supranuclear palsy (PSP)
2. Clinical diagnosis of dementia
3. Recent bladder medication
4. Implantable electronic device
5. Abnormality of both lower limbs
6. Limited life expectancy
7. Severe BPH or history of urological cancer

Date of first enrolment
02/09/2021

Date of final enrolment
09/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
RICE
Royal United Hospital
Coombe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Gatsby Charitable Foundation

Alternative Name(s)
THE GATSBY CHARITABLE FOUNDATION, GATSBY

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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 Dr Matthew Smith (matthew.smith@bristol.ac.uk) after August 2024.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/04/2025	20/05/2025	Yes	No
Protocol article		28/10/2022	31/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes