ISRCTN14509154 https://doi.org/10.1186/ISRCTN14509154

Study evaluating the blood pressure lowering efficacy and safety of a novel self-administered device-based treatment (by stimulating nerves that control blood pressure) in participants with uncontrolled hypertension.

Submission date 16/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/03/2022	**Overall study status** Completed	
Last Edited 29/09/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Hypertension/High blood pressure (BP) is the leading risk factor for death and illness from a cardiovascular event (e.g. heart attack), and managing high BP is a key focus of treatment for cardiovascular diseases. Antihypertensive drugs (drugs that aim to lower BP) are widely available, however a high number of people with high BP fail to achieve a healthy BP value despite receiving 1 or more anti-hypertensive medications. For uncontrolled hypertensive patients, including drug-resistant patients, the lack of an effective therapy is a major health challenge and an urgent unmet clinical need.

One potentially highly effective strategy to improve BP control in hypertension is via redressing the nervous system imbalance, which is linked with the development of hypertension; the brain controls the cardiovascular system by sending commands through the nervous system.
In this study, we will utilise a device that produces a very small electrical current to the nerves at the front area of the ears (the tragus). With this strategy, we aim to redress the nervous system imbalance and treat hypertension.

Who can participate?
Adults over 18 years and under 80 years, with high blood pressure.

What does the study involve?
Participants will be randomly allocated to receive the active or the inactive device in a 2:1 ratio (neither the clinical study team nor the participants will know who will receive the active device and who will receive the inactive). The participants will be asked to use the device for 30 minutes, daily for the first 14 days of the study, and then, once weekly for 10 weeks. The aim of the study is to establish that the device is safe, easy to use and acceptable by the patient, and that it has the potential to lower blood pressure in hypertensive patients.

What are the possible benefits and risks of participating?
Participants will be aggressively monitored during the trial period, and will have benefit of early treatment should their blood pressures go out of the allowable limits. The device used in this proposed study is similar to the products commonly available for pain relief, except it uses a different algorithm to deliver nerve stimulation. We are using this modified device for another indication; controlling blood pressure. No serious or life-threatening risks related to the use of this device are known; most available data suggest that this device is safe and, in a few participants, can cause transient and mild tingling, local skin irritation and at times, headaches.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
January 2021 to September 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Ajay K Gupta, ajay.gupta@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ajay Gupta

ORCID ID
https://orcid.org/0000-0001-5807-8503

Contact details
Barts CVCTU
William Harvey Research Centre
QMUL
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 2078822858
ajay.gupta@qmul.ac.uk

Type(s)
Scientific

Contact name
Ms Alexandra Papa

Contact details

Barts CVCTU
William Harvey Research Centre
QMUL
Charterhouse Square
London
United Kingdom
EC1M 6BQ
-
a.papa@qmul.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT05179343

Integrated Research Application System (IRAS)
302061

Central Portfolio Management System (CPMS)
51314

National Institute for Health and Care Research (NIHR)
202116

Protocol serial number
Sponsor ref: 2358563

Study information

Scientific Title
Sham controlled Randomized Controlled Trial evaluating the Safety, Acceptability and Efficacy of Autonomic neuromodulation using trans-cutaneous vagal sensory stimulation in uncontrolled hypertensive patients: a pilot study evaluating a novel non-invasive device-based strategy.

Acronym
SCRATCH HTN

Study objectives
Transcutaneous autonomic neuromodulation (tAN) treatment is safe and acceptable to the patient, improves the control of blood pressure in hypertension and sense of well-being amongst those who are receiving the active treatment as compared to those on sham treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2022, West of Scotland Research Ethics Service, West of Scotland REC 4 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC4@ggc.scot.nhs.uk), ref: 21/WS/0157

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Uncontrolled high blood pressure

Interventions
This is a randomised, sham-controlled study designed to evaluate the safety, acceptability, and efficacy of tAN in a cohort of uncontrolled medicated hypertensive patients.
The study is a single-site, pilot study evaluating a novel non-invasive device-based strategy to treat hypertension.

Investigational device: Transcutaneous Autonomic Neuromodulation (tAN) device (Affex-CT), reffered to as tAN device or tAN treatment. This device produces a low electrical current and will be attached to the tragus of both ears of the study participants. We expect the device to stimulate specific nerves of the nervous system and reduce the sympathetic (stimulatory) nervous system, leading to a decrease in Blood Pressure (BP).

SCRATCH-HTN trial is designed to test the hypothesis that tAN treatment is safe and acceptable to the patient, improves the control of blood pressure in hypertension and sense of well-being amongst those who are receiving the active treatment as compared to those on sham treatment (sham controlled).

Study population: Hypertensive (with uncontrolled BP) patients male or female aged ≥18 years and <80 years, taking between 1 to 3 antihypertensive medications, and who have one or more of the conditions:
-Obesity
-Type 2 Diabetes (controlled or sub-optimally controlled),
-Heart Rate ≥70 beats per minute,
-High levels of HbA1c (average blood glucose (sugar) levels for the last two to three months) or fasting blood glucose and low high density lipoprotein (HDL- the ‘good’ cholesterol) cholesterol or high triglyceride
-Low HDL and high triglyceride
-Polycystic ovarian syndrome.

The study will aim to recruit 63 patients with systemic arterial hypertension (male and female aged ≥18 years) who are receiving between one and three oral antihypertensive medications and remain hypertensive. The participants will be randomly allocated to the active (tAN) or sham (sham-tAN) arms of the trial on 2:1 basis.
26 of the participants recruited into the SCRATCH-HTN main trial will be invited to take part in the SCRATCH-HTN substudy. The aim of the sub study will be to further assess the nervous system function; this will provide the investigation team with insights about which components of the nervous system functions are affected by the treatment.
Participants will be screened within 28 days of their baseline/randomisation visit (visit 2/Day 0). The study will consist of 5 outpatient visits; visit 1 (screening visit), visit 2 (Day 0), visit 3 (Day 14),

visit 4 (Day 28) and visit 5 (end of treatment visit- Day 84). On day 0, participants will self-administer the study device for the first time. The total treatment duration is 12 weeks. The participants will self-administer the device for 30 minutes once per day for the first two weeks, and then once every week for the rest of the trial (10 weeks). 4 weeks after visit 5, participants will receive a follow-up phone call.

Participants will also be contacted by phone once between days 1-4, and on days 7 and 56. During these calls the clinical study team will be enquire how the participants are doing with self-administering the device treatment, and will assess them for any adverse effects, take note of their medications, and remind them about the device administration procedure and use of log book (a log that will be used by participants to record the use of the device and their health condition). Participants will also receive sms or email reminders to complete the device administration procedure and device logbook entry on days 42 and 70.

During the studies the following assessments will be conducted:
Height, weight & waist measurements, Vital signs – temperature, pulse, respiration rate, blood pressure, 24 hour BP and heart monitoring, Heart scans (Electrocardiogram, and Echocardiogram (which is an ultrasound scan of the heart)), blood tests, urine analysis, 6 minute walk test, questionnaires (Extent of adherence questionnaire (EoA) to confirm that participants have been complying with their treatment regimen, Insomnia Severity Index (ISI) questionnaire to check the quality of sleep, Blinding questionnaire to ask participant to answer if they think they receive the active or the inactive treatment , Device Usability questionnaire to ask if participants if the device is easy and acceptable to use, Quality of Life Questionnaire (EQ-5D QoL) to check how well participants feel after commencing the treatment), cognitive assessment to evaluate mental abilities.
Participants in the sub-study will also complete a central BP test (a non-invasive and painless procedure that measures the pressure of the largest artery in the human body- the aorta), and Autonomic Target-organs Neurophysiological tests (ATONT- a non-invasive treatment that enables to assess the nervous system function). These assessments will be done in addition to the main study assessments, on visits 2 and 5.

Investigation site and Patient Identification Centers (PICs):Participant recruitment and all trial activities will take place within an NHS setting at the William Harvey Clinical Research Centre (CRC) – the Investigation site.

The following recruitment strategies might be used:
1. Specialist clinics at Barts Health NHS Trust sites
2. Internal site participant database
3. Email/ electronic information leaflet will be sent to Barts/QMUL staff to inform them about the study.
4. PIC sites in secondary and primary care (see below).
5. Social media recruitment
6. Direct referral by a treating clinician

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Trans-cutaneous vagal sensory stimulation

Primary outcome(s)
Mean change in daytime ambulatory Systolic Blood Pressure (SBP) measured using sphymomanometer at baseline and end of the treatment (3 months)

Key secondary outcome(s)
1. Change in average daytime ambulatory SBP and Diastolic Blood Pressure (DBP) from baseline and 1 month. [Time Frame: from baseline to 1 month] Daytime ambulatory SBP values will be obtained with 24hr ABPM
2. Change in average daytime ambulatory DBP from baseline to the end of treatment. [Time Frame: from baseline to 3 months] Daytime ambulatory DBP values will be obtained with 24hr ABPM
3. Controlled BP at the end of treatment defined as mean daytime ambulatory SBP<135 mmHg and mean daytime ambulatory DBP<85 mmHg. [Time Frame: from baseline to 3 months] Daytime ambulatory SBP and DBP will be obtained with 24hr ABPM
4. Change in average 24-hour ambulatory SBP and DBP from baseline to the end of treatment. [Time Frame: from baseline to 3 months] Daytime ambulatory SBP and DBP will be obtained with 24hr ABPM
5. Change in average office SBP and DBP from baseline to 1 month, and from baseline to the end of treatment (3 months). [Time Frame: baseline to 1 month and baseline to 3 months] Daytime ambulatory SBP and DBP will be obtained with a vital signs monitor
6. Change in average daytime ambulatory HR, and in average night-time ambulatory HR from baseline to the end of treatment. [Time Frame: from baseline to 3 months]Daytime and nigh-time ambulatory HR will be obtained with 24hr ABPM
7. Change in BP variability defined as the coefficient of variation (SD/mean) of 24-hour ambulatory SBP, and of within-visit office SBP from baseline to the end of treatment. [Time Frame: from baseline to 3 months] 24hr ambulatory SBP will be obtained with 24hr ABPM
8. Change in Heart Rate (HR) variability defined as the coefficient of variation (SD/mean) of 24-hour ambulatory HR, and of within-visit office HR from baseline to the end of treatment. [Time Frame: from baseline to 3 months] 24hr ambulatory HR will be obtained with 24hr ABPM
9. Occurrence of a serious adverse event (SAE), fatal or non-fatal, within 3 months. [Time Frame: from baseline to 3 months]SAEs will be collected through patient interviews, reporting and monitoring
10. The occurrence of a major cardiovascular event (MACE), including myocardial infarction (MI), stroke, and cardiovascular-related mortality within 3 months. [Time Frame: from baseline to 3 months] MACE will be collected through patient interviews, reporting and monitoring
11. Change in Quality of life between baseline and the end of the treatment (3 months) using the EuroQol Visual Analogue score (0-100), and the EuroQol 5 Dimension (EQ5D) quality of life (QoL) questions. [Time Frame: from baseline to 3 months] EQ-5D-5L questionnaire
12. Change in sleep quality between baseline and the end of the treatment using the Insomnia Severity Index (ISI), a 7-item questionnaire with each question allowing responses on a 5-point Likert scale from 0-4. Responses summed to give an overall score of 0 [Time Frame: from baseline to 3 months] ISI questionnaires
13. Adherence to trial therapy, assessed as the proportion of days out of total days in follow-up when therapy was self-administered, and the average daily duration of self-administered therapy over the 3 months of follow-up (90 days). [Time Frame: from baseline to 3 months] Study log-book

Completion date
08/09/2025

Eligibility

Key inclusion criteria

Current inclusion criteria as of 30/12/2025:

1. Participant has given written informed consent.
2. Participant has sufficient knowledge of the English language to be able understand the participant information sheet and trial materials including outcome assessments.
3. Participant is aged ≥18 years and <80 years at the time of screening visit.
4. Participant is taking between 1 to 4 antihypertensive medications (inclusive) at time of screening and baseline (randomisation) visit and is willing to adhere to no change in medication during the trial until end of the trial visit (visit 5). (NB. Participant on only one antihypertensive medication should be taking that medication for at least six weeks
prior to the screening visit).
5. Participant has confirmed diagnosis of hypertension.
6. Participant meets BP criteria:
• 24-hour ambulatory BP monitoring (ABPM) at either screening visit or baseline (randomisation) visit, with mean daytime SBP of ≥135 mmHg and <170 mmHg and mean daytime DBP of >85 mm Hg and <115 mmHg (N.B. By default, Ambulatory Blood Pressure Monitoring [ABPM] at screening visit will be used at baseline visit. However, if there has been an addition of new medication after participant's screening visit, 24-hour ABPM must be repeated at baseline visit, but the screening ABPM will be used for eligibility criteria).
7. Participant has one or more of the following associated conditions:
7.1. Obesity: BMI >30 or waist circumference >94 cm (men) or > 80cm (women). (NB. For participants of South-East Asian/Chinese/Japanese origin these cut-offs are >90 cm (men) or >80 cm (women)).
7.2. Type 2 diabetes – controlled or sub-optimally controlled (HbA1c ≤8.5% or ≤69 mmol/mol) on diet and/ or medications except insulin.
7.3. Heart rate (any one of the three recordings) ≥70 bpm at screening or baseline (randomisation) visit (measurements taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter) or a heart rate (any one of the three recordings) ≥60 bpm at screening or baseline (randomisation) visit if the patient is taking beta-blocker medication or a rate-limiting calcium channel-blocker medication.
7.4. HbA1c ≥42 mmol/mol or fasting blood glucose (if available) ≥5.6 mmol/L AND either low HDL cholesterol (≤1.03 mmol/L for men and ≤1.29 mmol/L for women) or high triglyceride (triglycerides ≥1.7 mmol/L)
7.5. Both low HDL cholesterol (≤1.03 mmol/L for men and ≤1.29 mmol/L for women) AND high triglyceride (triglycerides ≥1.7 mmol/L)
7.6. Diagnosed or known case of polycystic ovarian syndrome.
8. Female participants of child-bearing potential (all those below 55 years except if they are surgically sterile, meaning they have undergone a hysterectomy, bilateral tubal ligation, or bilateral oophorectomy, or formally diagnosed by their doctors to be postmenopausal) must agree to use the acceptable methods of contraception from the time of consent until last follow up visit.
9. Participant is able to communicate satisfactorily with the Investigator and Investigation Site staff, and to participate in, and comply with all clinical study requirements.
10. Participants agrees to have all trial procedures performed and is able and willing to comply with all trial visits and protocol requirements.

Previous inclusion criteria as of 17/04/2024:

1. Participant has given written informed consent.
2. Participant has sufficient knowledge of the English language to be able to understand the participant information sheet and trial materials including outcome assessments.
3. Participant is aged ≥18 years and <80 years at the time of screening visit.
4. Participant is taking between 1 to 4 antihypertensive medications (inclusive) at time of screening and baseline (randomisation) visit and is willing to adhere to no change in medication during the trial until end of the trial visit (visit 5). (NB. Participant on only one antihypertensive medication should be taking that medication for at least six weeks prior to the screening visit).
5. Participant has confirmed diagnosis of hypertension.
6. Participant meets the following BP criteria: 24-hour ambulatory BP monitoring (ABPM) at either screening visit or baseline (randomisation) visit, with mean daytime SBP of ≥135 mmHg and <170 mmHg and mean daytime DBP of >85 mm Hg and <115 mmHg (N.B. By default, Ambulatory Blood Pressure Monitoring [ABPM] at screening visit will be used at baseline visit. However, if there has been an addition of new medication after participants screening visit, 24-hour ABPM must be repeated at baseline visit).
7. Participant has one or more of the following associated conditions:
7.1. Obesity: BMI >30 OR waist circumference >94 cm (men) or > 80cm (women). (NB. For participants of South-East Asian/Chinese/Japanese origin these cut-offs are >90 cm (men) or >80 cm (women)).
7.2. Type 2 diabetes – controlled or sub-optimally controlled (HbA1c ≤8.5% or ≤69 mmol/mol) on diet and/ or medications except insulin.
7.3. Heart rate (on any one of the three heart rate recordings at that visit) ≥70 bpm at screening or baseline (randomisation) visit (measurements taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter) or a heart rate (on any one of the three heart rate recordings) ≥60 bpm at screening or baseline (randomisation) visit if the patient is taking beta-blocker medication.
7.4. HbA1c ≥42 mmol/mol or fasting blood glucose (if available) ≥5.6 mmo/L, and either low HDL cholesterol (≤1.03 mmol/L for men and ≤1.29 mmol/L for women) or high triglyceride (triglycerides ≥1.7 mmol/L)
7.5. Both low HDL cholesterol (≤1.03 mmol/L for men and ≤1.29 mmol/L for women) and high triglyceride (triglycerides ≥1.7 mmol/L)
7.6. Diagnosed or known case of polycystic ovarian syndrome.
8. Female participant of child-bearing potential (all those below 55 years except if they are surgically sterile, meaning they have undergone a hysterectomy, bilateral tubal ligation, or bilateral oophorectomy, or formally diagnosed by their doctors to be post-menopausal) must agree to use the acceptable methods of contraception from the time of consent until last follow up visit.
9. Participant is able to communicate satisfactorily with the Investigator and Investigation Site staff, and to participate in, and comply with all clinical study requirements
10. Participant agrees to have all trial procedures performed and are able and willing to comply with all trial visits and protocol requirements

———

Previous inclusion criteria:

1. Participant has given written informed consent.
2. Participant has sufficient knowledge of the English language to be able to understand the participant information sheet and trial materials including outcome assessments.
3. Participant is aged >=18 years and <80 years at the time of screening visit.
4. Participant is taking between 1 to 3 antihypertensive medications (inclusive) at time of screening and baseline (randomisation) visit and is willing to adhere to no change in medication

during the trial until end of the trial visit (visit 5). (NB. Participant on only one antihypertensive medication should be taking that medication for at least six weeks prior to the screening visit).
5. Participant has confirmed diagnosis of hypertension.
6. Participant meets the following BP criteria:
6.1. 24-hour ambulatory BP monitoring (ABPM) at either screening visit or baseline (randomisation) visit, with mean daytime SBP of >=135 mmHg and <170 mmHg and mean daytime DBP of >85 mm Hg and <115 mmHg (N.B. By default, Ambulatory Blood Pressure Monitoring [ABPM] at screening visit will be used at baseline visit. However, if there has been an addition of new medication after participants screening visit, 24-hour ABPM must be repeated at baseline visit) AND
6.2. Mean office BP (which is mean of last two readings from 3 BP recordings) with recorded SBP of >=140 mmHg and <180 mmHg and DBP >=90 mmHg and <120 mmHg at screening or baseline (randomisation) visit (either one of the two visits or both).
7. Participant has one or more of the following associated conditions:
7.1. Obesity: BMI >30 kg/m² OR waist circumference >94 cm (men) or >80cm (women). (NB. For participants of South-East Asian/Chinese/Japanese origin these cut-offs are >90 cm (men) or >80 cm (women)).
7.2. Type 2 diabetes – controlled or sub-optimally controlled (HbA1c <=8.5% or <=69 mmol/mol) on diet and/ or medications except insulin.
7.3. Heart rate (average) >=70 bpm at screening or baseline (randomisation) visit (measurement taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter) or a heart rate (average) >=60 bpm at screening or baseline (randomisation) visit if the patient is taking beta-blocker medication.
7.4. HbA1c >=42 mmol/mol or fasting blood glucose (if available) >=5.6 mmo/L, and either low HDL cholesterol (<=1.03 mmol/L for men and <=1.29 mmol/L for women) or high triglyceride (triglycerides >=1.7 mmol/L)
7.5. Both low HDL cholesterol (<=1.03 mmol/L for men and <=1.29 mmol/L for women) and high triglyceride (triglycerides >=1.7 mmol/L)
7.6. Diagnosed or known case of polycystic ovarian syndrome.
8. Female participant of child-bearing potential (all those below 55 years except if they are surgically sterile, meaning they have undergone a hysterectomy, bilateral tubal ligation, or bilateral oophorectomy, or formally diagnosed by their doctors to be post-menopausal) must agree to use the acceptable methods of contraception from the time of consent until last follow up visit.
9. Participant is able to communicate satisfactorily with the Investigator and Investigation Site staff, and to participate in, and comply with all clinical study requirements.
10. Participant agrees to have all trial procedures performed and are able and willing to comply with all trial visits and protocol requirements.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
79 Years

Sex
All

Total final enrolment
63

Key exclusion criteria
Current exclusion criteria as of 30/12/2025:

1. Participant is unable and unwilling to use the AffeX-CT device daily.
2. Participant has a small tragus (ie. the size or shape of the tragus is such that it doesn't allow the application of the ear-clips of the AffeX-CT device for a sustained period of time).
3. Participant has a piercing on the tragus of the ear.
4. Participant is diagnosed with atrial fibrillation or other form of cardiac arrhythmia
5. Participant has eGFR <45 ml/min/1.73 m2 at screening visit.
6. Participant has type 1 diabetes mellitus.
7. Participant has type 2 diabetes mellitus on Insulin or those on oral antidiabetic medications with poor glycaemic control defined as HbA1c above 8.5% (or >69 mmol/mol).
8. Participant has a history of falls or symptoms of orthostatic hypotension in the last 3 months prior to baseline (randomisation) visit.
9. Participant is pregnant, nursing or planning to become pregnant within the next 6 months.
10. Participant suffers from chronic pain and has taken anti-inflammatory drugs for two or more days per week over the last month prior to baseline (randomisation) visit.
11. Participant has clinically significant or symptomatic hypertension-mediated target organ damage such as severe heart failure with NYHA 4, end stage renal damage, medically diagnosed /imaging proven stroke, symptomatic peripheral vascular disease, or severe retinopathy.
12. Participant has a history of stable or unstable angina or had an acute coronary event within 3 months prior to baseline (randomisation) visit or had a myocardial infarction within the last 6 months of enrolment prior to baseline (randomisation) visit.
13. Participant has history of renal denervation within 1 year prior to baseline (randomisation) visit.
14. Participant has a therapeutic implantable electronic/electrical device such as pacemaker, implantable cardioverter-defibrillators (ICDs), implanted vagal stimulators.
15. Participant has history of hospitalization (> 24 hour) for heart failure, or cerebrovascular accidents, or history of stroke diagnosed based on imaging or evidence of specialist diagnosis or any other indirect evidence such as discharge summary or clinical letter (at any time in the past).
16. Participant has mean daytime ABPM pulse pressure ≥ 80 mmHg at screening or baseline (randomisation) visit.
17. Participant has a heart rate <50 bpm at screening or baseline (randomisation) visit (measurement taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter).
18. Participant has auricular dermatitis.
19. Participant has postural hypotension, defined as a fall > 20mmHg in SBP on standing at 3 minutes (compared with sitting).
20. Participant has a history of hospitalisation for hypertensive emergency or urgency in the last 6 months of enrolment prior to baseline (randomisation) visit. 'Hospitalisation' is defined as admission for more than 24 hours or between 12-24 hours with an overnight stay.

21. Participant is identified as unsuitable to participate by the CI/Sub-Investigator(s) and/or Investigation site team for another reason (e.g., for other medical reasons, laboratory abnormalities, limited life expectancy, etc).
22. Participants with history of epilepsy and are currently on anti-epileptic medication or those who are not on any anti-epileptic medication but have history of a seizure within last 10 years.

Previous exclusion criteria as of 17/04/2024:

1. Participant is unable and unwilling to use AffeX-CT device daily.
2. Participant has a small tragus (ie. the size or shape of the tragus is such that it doesn't allow the application of the ear-clips of the AffeX-CT device for a sustained period of time).
3. Participant has a piercing on the tragus of the ear.
4. Participant is diagnosed with atrial fibrillation or other form of cardiac arrhythmia.
5. Participant has eGFR <45 ml/min/1.73 m2 at screening visit.
6. Participant has type 1 diabetes mellitus.
7. Participant has type 2 diabetes mellitus on Insulin or those on oral antidiabetic medications with poor glycaemic control defined as HbA1c above 8.5% (or >69 mmol/mol).
8. Participant has a history of falls or symptoms of orthostatic hypotension in the last 3 months prior to baseline (randomisation) visit.
9. Participant is pregnant, nursing or planning to become pregnant within the next 6 months.
10. Participant suffers from chronic pain and has taken anti-inflammatory drugs for two or more days per week over the last month prior to baseline (randomisation) visit.
11. Participant has clinically significant or symptomatic hypertension-mediated target organ damage such as severe heart failure with NYHA 4, end stage renal damage, medically diagnosed /imaging proven stroke, symptomatic peripheral vascular disease, or severe retinopathy.
12. Participant has a history of stable or unstable angina or had an acute coronary event within 3 months prior to baseline (randomisation) visit or had a myocardial infarction within the last six months of enrolment prior to baseline (randomisation) visit.
13. Participant has a history of renal denervation within last 1 year prior to baseline (randomisation) visit.
14. Participant has a therapeutic implantable electronic/electrical device such as pacemaker, implantable cardioverter-defibrillators (ICDs), implanted vagal stimulators.
15. Participant has history of hospitalization (> 24 hour) for heart failure, or cerebrovascular accidents, or history of stroke diagnosed based on imaging or evidence of specialist diagnosis or any other indirect evidence such as discharge summary or clinical letter (at any time in the past).
16. Participant has mean daytime ABPM pulse pressure ≥ 80 mmHg at screening or baseline (randomisation) visit.
17. Participant has a heart rate <50 bpm at screening or baseline (randomisation) visit (measurement taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter).
18. Participant has auricular dermatitis.
19. Participant has postural hypotension, defined as a fall > 20mmHg in SBP on standing at 3 minutes (compared with sitting).
20. Participant has a history of hospitalisation for hypertensive emergency or urgency in the last six months of enrolment prior to baseline (randomisation) visit.
21. Participant is identified as unsuitable to participate by the CI/Sub-Investigator(s) and/or Investigation site team for another reason (e.g., for other medical reasons, laboratory abnormalities, limited life expectancy, etc.)
22. Participants with history of epilepsy and are currently on anti-epileptic medication or those who are not on any anti-epileptic medication but have history of a seizure within last 10 years.

Previous exclusion criteria:

1. Participant is unable and unwilling to use the AffeX-CT device daily.
2. Participant has a small tragus (ie. the size or shape of the tragus is such that it doesn't allow the application of the ear-clips of the AffeX-CT device for a sustained period of time).
3. Participant has a piercing on the tragus of the ear.
4. Participant is diagnosed with atrial fibrillation or other form of cardiac arrhythmia
5. Participant is known to have chronic kidney disease (CKD) stage 3b or higher or had eGFR <45 ml/min/1.73 m^2 in last three months prior to baseline (randomisation) visit.
6. Participant has type 1 diabetes mellitus.
7. Participant has type 2 diabetes mellitus on Insulin or those on oral antidiabetic medications with poor glycaemic control defined as HbA1c above 8.5% (or >69 mmol/mol).
8. Participant has a history of falls or symptoms of orthostatic hypotension in the last 3 months prior to baseline (randomisation) visit.
9. Participant is pregnant, nursing or planning to become pregnant within the next 6 months.
10. Participant suffers from chronic pain and has taken anti-inflammatory drugs for two or more days per week over the last month prior to baseline (randomisation) visit.
11. Participant has significant (or symptomatic) target organ damage including symptomatic heart failure, renal damage, symptomatic peripheral vascular disease, or severe retinopathy.
12. Participant has a history of stable or unstable angina or had an acute coronary event within 3 months prior to baseline (randomisation) visit or had a myocardial infarction within the last six months of enrolment prior to baseline (randomisation) visit.
13. Participant has history of renal denervation within 1 year prior to baseline (randomisation) visit.
14. Participant has an implantable electronic/electrical device such as pacemaker, implantable cardioverter-defibrillators (ICDs), implanted vagal stimulators.
15. Participant has history of hospitalization for heart failure, cerebrovascular accidents, or stroke (at any time in the past).
16. Participant has mean office pulse pressure ≥80 mmHg (mean of the last two of the three readings) at screening or baseline (randomisation) visit.
17. Participant has a heart rate <50 bpm at screening or baseline (randomisation) visit (measurement taken after 5 minutes of rest in a seated position and when finger probe has been placed for a minimum of 30 seconds thereafter).
18. Participant has auricular dermatitis.
19. Participant has postural hypotension, defined as a fall >20mmHg in SBP on standing at 3 minutes (compared with sitting).
20. Participant has a history of hospitalization for hypertensive emergency or urgency in the last six months of enrolment prior to baseline (randomisation) visit.
21. Participant is identified as unsuitable to participate by the CI/Co-Investigator(s) and/or Investigation site team for another reason (e.g., for other medical reasons, laboratory abnormalities, limited life expectancy, etc.).
22. Participants with history of epilepsy and are currently on anti-epileptic medication or those who are not on any anti-epileptic medication but have history of a seizure within last 10 years

Date of first enrolment
01/08/2022

Date of final enrolment
14/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
England
E9 6SR

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Study participating centre
St George's University Hospitals NHS Foundation Trust
Cranmer Terrace
London

England
SW17 0RE

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
England
CM1 7ET

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study and to be analysed at study closure for SCRATCH-HTN will be available upon reasonable request after an embargo period of 12 months from the date of publication of main findings from the CI (Dr Ajay Gupta, ajay.gupta@qmul.ac.uk). The data to be shared will be processed and anonymised data and will be available after 1 year from the publication of the main findings for a further period of 5 years, and all study participants have consented to this data sharing. Afferent Medical Solutions will have access to anonymised data as a commercial partner in the study and for the MHRA regulatory and licencing requirements. Other requests for access to SCRATCH-HTN data should specify the reason for the request and how the data will be processed, and the data will be shared using secure data transfer methods to ensure all ethical and legal restrictions are met.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/04/2026	24/04/2026	Yes	No
Basic results		24/09/2026	29/09/2026	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			29/09/2026	No	Yes
Statistical Analysis Plan	version 2.0	22/04/2025	29/09/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes