

# 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.

<b>Submission date</b> 16/02/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/03/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/04/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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 December 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](mailto:ajay.gupta@qmul.ac.uk)

### **Study website**

<https://www.qmul.ac.uk/whri/research/scratch-htn/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Ajay Gupta

### **ORCID ID**

<http://orcid.org/0000-0001-5807-8503>

### **Contact details**

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### **Type(s)**

Scientific

### **Contact name**

Ms Alexandra Papa

**Contact details**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

302061

**ClinicalTrials.gov number**

NCT05179343

**Secondary identifying numbers**

CPMS 51314, NIHR 202116, IRAS 302061, 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

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

University/medical school/dental school, Other

**Study type(s)**

Treatment, Safety, Efficacy

**Participant information sheet**

[https://www.qmul.ac.uk/whri/media/the-william-harvey-research-institute/documents/SCRATCH-HTN-PIS-with-consent-\(clean\)-V7.0-31JAN24.pdf](https://www.qmul.ac.uk/whri/media/the-william-harvey-research-institute/documents/SCRATCH-HTN-PIS-with-consent-(clean)-V7.0-31JAN24.pdf)

**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), referred 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  $\geq 18$  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  $\geq 70$  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  $\geq 18$  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 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

## **Pharmaceutical study type(s)**

Not Applicable

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Trans-cutaneous vagal sensory stimulation

## **Primary outcome measure**

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

## **Secondary outcome measures**

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 night-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

### **Overall study start date**

10/01/2021

### **Completion date**

31/12/2025

## **Eligibility**

### **Key inclusion criteria**

Current 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  $\geq 18$  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  $\geq 135$  mmHg and  $< 170$  mmHg and mean daytime DBP of  $> 85$  mmHg 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  $> 80$  cm (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  $\leq 8.5\%$  or  $\leq 69$  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)  $\geq 70$  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)  $\geq 60$  bpm at screening or baseline (randomisation) visit if the patient is taking beta-blocker medication.
  - 7.4. HbA1c  $\geq 42$  mmol/mol or fasting blood glucose (if available)  $\geq 5.6$  mmol/L, and either low HDL cholesterol ( $\leq 1.03$  mmol/L for men and  $\leq 1.29$  mmol/L for women) or high triglyceride

(triglycerides  $\geq 1.7$  mmol/L)

7.5. Both low HDL cholesterol ( $\leq 1.03$  mmol/L for men and  $\leq 1.29$  mmol/L for women) and high triglyceride (triglycerides  $\geq 1.7$  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

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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  $\geq 18$  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  $\geq 135$  mmHg and  $< 170$  mmHg and mean daytime DBP of  $\geq 85$  mmHg 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  $\geq 140$  mmHg and  $< 180$  mmHg and DBP  $\geq 90$  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/m<sup>2</sup> OR waist circumference  $> 94$  cm (men) or  $> 80$  cm (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  $\leq 8.5\%$  or  $\leq 69$  mmol/mol) on diet and/ or medications except insulin.

7.3. Heart rate (average)  $\geq 70$  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)  $\geq 60$  bpm at screening or baseline (randomisation) visit if the patient is taking beta-blocker medication.

7.4. HbA1c  $\geq 42$  mmol/mol or fasting blood glucose (if available)  $\geq 5.6$  mmol/L, and either low HDL cholesterol ( $\leq 1.03$  mmol/L for men and  $\leq 1.29$  mmol/L for women) or high triglyceride (triglycerides  $\geq 1.7$  mmol/L)

7.5. Both low HDL cholesterol ( $\leq 1.03$  mmol/L for men and  $\leq 1.29$  mmol/L for women) and high triglyceride (triglycerides  $\geq 1.7$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

79 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 63; UK Sample Size: 63

**Key exclusion criteria**

Current 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 m<sup>2</sup> 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  $\geq 80$  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.

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#### 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<sup>2</sup> 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  $\geq 80$  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  $> 20$  mmHg 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**

30/04/2025

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**The Royal London Hospital**

80 Newark Street

London

United Kingdom

E1 2ES

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**

250 Euston Road

London

United Kingdom

NW1 2PG

**Study participating centre****Homerton University Hospital NHS Foundation Trust**

Homerton Row  
London  
United Kingdom  
E9 6SR

**Study participating centre****Imperial College Healthcare NHS Trust**

The Bays  
St Marys Hospital  
South Wharf Road  
London  
United Kingdom  
W2 1BL

**Study participating centre****St George's University Hospitals NHS Foundation Trust**

Cranmer Terrace  
London  
United Kingdom  
SW17 0RE

**Study participating centre****Royal Free London NHS Foundation Trust**

Royal Free Hospital  
Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre****Broomfield Hospital**

Court Road  
Broomfield  
Chelmsford  
United Kingdom  
CM1 7ET

**Sponsor information**

**Organisation**

Queen Mary University of London

**Sponsor details**

327, Mile End Road

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+44 2078827260

research.governance@qmul.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.qmul.ac.uk/>

**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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/12/2026

## 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](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No