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Sodium effect on aldosterone in real time

Submission date 04/10/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 07/10/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypertension is a major cause of both mortality and morbidity in the UK. Oversecretion of the hormone aldosterone is implicated in around 30% of cases of hypertension seen in secondary health care. At present, very few of these patients with hyperaldosteronism are diagnosed, as the protocols for diagnosis are complex and invasive. A recent study developed a technique for the continuous monitoring of aldosterone using a novel device called U-Rhythm and found that this was able to differentiate abnormal aldosterone secretion in many cases. To improve diagnostic efficiency, a study is required to show whether changing the dietary input of salt inhibits aldosterone secretion in normal subjects but not in people with hyperaldosteronism. Firstly, however, a pilot study is required to see how changes in salt intake alter the 24-hour regulation of aldosterone in normal subjects. This study aims to assess whether a high or low salt diet affects aldosterone levels for a healthy individual over 24 hours.

Who can participate?
Healthy adult volunteers

What does the study involve?
The project involves recruiting participants and asking them to adhere to a high or low salt diet for 7 days before using the U-Rhythm technique to monitor aldosterone (and additional hormones) for 24 hours. The study will also collect a 24-hour urine sample to measure sodium and aldosterone levels, and blood tests for renin and aldosterone (lying and standing) and renal function (including electrolytes).

Additionally, participants will be asked to exercise on a static bike as aldosterone has been shown to change after exertion. After a washout period, the process will be repeated, following 7 days of adhering to the alternate diet. All dietary regimens have been prepared by NHS dietitians and will be balanced in all other nutritional components.

What are the possible benefits and risks of participating?
Results of tests will be offered to participants and, if an abnormality is uncovered and if consent is given, we will contact the participant's GP to update them of the finding. Some participants may see the VO2 peak test as a benefit.

There are no significant legal, ethical or management issues arising from this study. This study will present minimal risk to participants. The microdialysis procedure has previously been conducted in hundreds of participants with no significant adverse events (e.g. ULTRADIAN, REC 16/SW/0069, NCT02934399; REC 47081; REC 77081, Bhake et al. 2013, Bhake et al. 2019, Bhake et al. 2020, Upton et al. 2023). There is a possibility of minor bruising at the site of the microdialysis probe insertion. The procedure is minimally invasive. A fine catheter is inserted just beneath the surface of the skin using aseptic technique. The catheter remains in place for approximately 24 hours, and the risk of infection is considered minimal. The probe, microdialysis pump and accessories used for the subcutaneous tissue collection device are commercially available (CE marked), and no problems are anticipated in relation to these items. The CGMS sensor is a CE-marked device. This is inserted into clean skin of the abdomen or arm by the study investigator (contralateral side to the microdialysis probe) following the manufacturer's recommended standard procedure. This is considered a very low-risk procedure. All other sensors are non-invasive and simply require contact with the skin. There is no anticipated risk associated with these devices. Blood samples will be collected by a suitably trained researcher. Aside from minor bruising or discomfort, the risk of this procedure is extremely small, and the total volume to be drawn will not exceed 50mL. This will not have any haemodynamic consequences. Participants will be asked to collect a 24-hour urine sample. This will not have any adverse effects.

Where is the study run from?
University of Bristol, UK

When is the study starting and how long is it expected to run for?
August 2024 to July 2027

Who is funding the study?
Bristol & Weston Hospitals Charity, UK

Who is the main contact?
salt-study@bristol.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354064

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of dietary sodium on aldosterone profile in health volunteers

Acronym
SALT

Study objectives
To assess whether altering dietary sodium intake affects the aldosterone pattern of a healthy individual over a 24-hour period.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2025, University of Bristol Faculty of Health Sciences Research Ethics Committee (FREC) (University of Bristol, Bristol, BS8 1QU, United Kingdom; -; research-ethics@bristol.ac.uk), ref: 21760

Study design
Single-centre non-blinded interventional randomized crossover trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Assessing whether altering dietary sodium intake affects the aldosterone pattern of a healthy individual over 24 hours.

Interventions

The intervention is modifying the salt content of the diet for 7 days with high and low salt diets (crossover). The low salt diet will contain < 1 gram of salt per day, and the high salt diet will contain > 10 grams of salt per day. Wash-out will be a minimum of 1 week washout period between arms. The order will be randomised using the research randomiser tool (randomizer. org). The microdialysis will occur during the final 24 hours on each dietary arm, plus serum tests and exercise protocol on the final day. No follow-up is planned after the participant has completed the second dietary arm.

Intervention Type
Other

Primary outcome(s)
Difference in aldosterone profiles measured using mass spectroscopy at the end of each dietary arm. A cosinor analysis will be undertaken of the 24-hour curves and dynamic markers, including: total area under the curve, magnitude of morning peak, number of peaks, or evening nadir.

Key secondary outcome(s))
1. Difference in the magnitude of the renin or aldosterone response to a change in posture measured using mass spectroscopy at the end of each dietary protocol (samples at 0, 20, 40, and 60 minutes standing)
2. Difference in magnitude of aldosterone response to exercise using microdialysis and serum tests at the end of 30 minutes on a static bike at 50-60% of VO2 peak
3. Difference in 24-hour urine aldosterone measured using mass spectrometry at the end of each dietary arm

Completion date
31/07/2027

Eligibility

Key inclusion criteria
Age 18-40

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex

All

Key exclusion criteria
1. A history of hypertension, hyperaldosteronism, obstructive sleep apnoea, or heart disease
2. Taking medication that could affect aldosterone levels. This includes most antihypertensives and common inhalers
3. Anyone with a 1st degree family member who was diagnosed with hypertension below the age of 60 or has a diagnosis of primary hyperaldosteronism
4. Inability to understand spoken or written instructions given in English
5. Body mass index ≥30 kg/m2
6. Pregnancy
7. Alcohol consumption (>28 units/week), daily use of nicotine (including smoking and vaping) and daily use of recreational drugs due to risk of withdrawal symptoms during lab visits
8. Needle phobia
9. Allergy to any ingredient within the meal plans, or dietary requirements that cannot be catered for within the meal plans
10. Anyone who has worked shifts finishing after midnight in the past 4 weeks
11. Anyone with irregular sleep times (i.e. bedtime/wake time varies by more than +- 1 hour across a normal week)

Date of first enrolment
05/10/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Bristol Clinical Research Facility
60 St Michael's Hill
Bristol
United Kingdom
BS2 8DX

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Bristol and Weston Hospitals Charity

Alternative Name(s)
Bristol & Weston Hospitals Charity, Above & Beyond

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 will be available upon request from Dr Tim Swinn (salt-study@bristol.ac.uk).

Upon request, we will share fully anonymised individual participant data after publication of our study. Participants will be asked to give consent for this before starting the study. This has been approved by the University of Bristol Ethics Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	31/07/2025	07/10/2025	No	Yes
Protocol file	version 3	07/10/2025	07/10/2025	No	No