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A study to identify increased production of aldosterone by the adrenal gland using PET/CT scanning techniques

Submission date
14/06/2022

Recruitment status
No longer recruiting

Registration date
22/07/2022

Overall study status
Completed

Last Edited
11/06/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
One of the most common causes of high blood pressure is primary hyperaldosteronism (PHA), a hormonal disorder that leads to overproduction of a hormone called aldosterone. Aldosterone usually balances sodium and potassium in the blood, however when too much of this hormone is produced more potassium is lost but the body retains the sodium. This imbalance can cause your body to hold too much water which in turn leads to a greater volume of blood and ultimately increased blood pressure.

One of the causes of PHA is a non-cancerous tumour that grows on the gland that produces aldosterone In these cases surgery to remove these glands can substantially reduce blood pressure and medication requirements and may result in a complete cure (30-60% of cases).

Currently, methods of diagnosis for this tumour are inefficient and often inconclusive; screening, such as CT scans and adrenal vein sampling (AVS) is used. AVS is challenging, invasive, has a poor success rate and is often not feasible as it requires patients with high blood pressure to stop medication for several weeks.

We have developed a molecule that will target an enzyme which acts as the main regulator of aldosterone secretion. It is labelled with a radioactive substance that Is regularly used in PET scanning. Patients with increased levels of this enzyme from the adrenal glands should absorb more of the molecule. As the molecule is radioactive, this will be detected by a Positron Emission Tomography/Computed Tomography (PET/CT) scanner and can be viewed by a radiologist.

We have trialled this in animals and found that the radiolabelled substance does target expression of the correct enzyme and can be given in quantities that should not be harmful to humans.

We would like to use this tracer in patients that have an aldosterone producing tumour, to illustrate this effect in humans, and as the patients will go on to have surgery we can examine

the adrenal tissue that has been removed to confirm that enzyme expression is related to uptake of the tracer.

Study Aims
1. To measure aldosterone synthase (the enzyme known as CYP11B2) levels in vivo
2. To make a preliminary analysis of the relationship between aldosterone production in vivo (as determined by adrenal vein sampling) and levels of aldosterone synthase (measured with PET).

Who can participate?
Patients that are due to have surgical resection of their unilateral adenoma will be eligible.

What does the study involve?
The primary activity for participants is to undergo PET/CT scan procedure following an injection of 18F-UCB2 which will take around 90 minutes.

What are the possible benefits and risks of participating?
There is a small risk associated with exposure to radioactivity, which has been assessed and deemed as acceptable.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
October 2021 to August 2023

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Erik Arstad, e.arstad@ucl.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
274695

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49883, IRAS 274695

Study information

Scientific Title
Image-Derived Enzymatic Adrenal Lateralisation of Primary Aldosteronism

Acronym
IDEAL

Study objectives
The use of a radiolabelled inhibitor of aldosterone synthase in combination with PET/CT scanning could elucidate assymetric uptake between adrenal glands, indicating presence of an aldosterone producing adenoma (APA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2021, London - Brent Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; brent.rec@hra.nhs.uk), ref: 21/LO/0521

Study design
Prospective mechanistic cohort study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Aldosterone producing adenoma

Interventions
The first four patients enrolled will undergo a 90 minute scan including dynamic injection of 18F-UCB2 in order to identify the optimal imaging time point for scanning. The second four patients will undergo the same procedure divided into separate imaging acquisitions in order to understand the biodistribution and dosimetry of the tracer. The third group will be scanned at the pre-determined optimal fixed time frame as determined for Objective A, and the tracer uptake will be determined by standardized uptake values (SUVs).

There will be no difference between participants in terms of eligibility, and will be included by order of identification.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Uptake of 18F-UCB2 by the adrenal glands measured using PET/CT scanning techniques following identification, and prior to surgery for adrenalectomy

Key secondary outcome(s))
Levels of aldosterone synthase identified post operatively in resected adrenals

Completion date
30/04/2024

Eligibility

Key inclusion criteria
Patients with a diagnosis of, and planned surgery for aldosternone producing adnemoma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
17

Key exclusion criteria
Inability to understand, or insufficient capacity to give informed consent.

Date of first enrolment
04/01/2022

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR University College London Hospitals Biomedical Research Centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
NW1 2PG

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Society for Endocrinology BES 2023	15/11/2023	11/04/2024	No	No
HRA research summary			28/06/2023	No	No
Plain English results		09/05/2025	11/06/2025	No	Yes