

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

<b>Submission date</b> 14/06/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

#### Contact name

Prof Erik Arstad

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

274695

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**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 measure**

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

**Secondary outcome measures**

Levels of aldosterone synthase identified post operatively in resected adrenals

**Overall study start date**

11/10/2021

**Completion date**

30/04/2024

**Eligibility**

**Key inclusion criteria**

Patients with a diagnosis of, and planned surgery for aldosterone producing adenoma

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

12

**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**

England

United Kingdom

**Study participating centre**

**NIHR University College London Hospitals Biomedical Research Centre**

University College London Hospitals NHS Foundation Trust

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**Sponsor information****Organisation**

University College London

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**Sponsor type**

University/education

**Website**

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

**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, MRC

**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**

01/03/2024

**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?
<a href="#">HRA research summary</a>	Society for Endocrinology BES 2023		28/06/2023	No	No
<a href="#">Abstract results</a>		15/11/2023	11/04/2024	No	No
<a href="#">Plain English results</a>		09/05/2025	11/06/2025	No	Yes