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A research study testing whether a single dose of [18F]AldoView can produce useful images of adrenal glands allowing identification of participants with and without primary aldosteronism

Submission date
18/02/2026

Recruitment status
Recruiting

Registration date
20/04/2026

Overall study status
Ongoing

Last Edited
07/05/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

High blood pressure is extremely common, and one important but often overlooked cause is primary aldosteronism (PA). PA occurs when adrenal glands produce too much of the hormone aldosterone which helps control the balance of sodium and potassium in the body. When aldosterone is overproduced, the body keeps too much sodium and water, leading to raised blood pressure, and loss of potassium. PA is treatable if doctors can identify the adrenal gland responsible.

The challenge is that the abnormal areas within the adrenal glands that produce excess aldosterone can be very small, making them difficult to detect using current tests. The standard test, adrenal vein sampling (AVS) is invasive, technically complex and not always successful. Existing positron emission tomography / computed tomography (PET/CT) scans have also been limited because older radiotracers could not reliably identify very small abnormalities.

This study will test AldoView, a new radiotracer designed to show areas of increased enzyme activity involved in aldosterone production. A radiotracer is a substance linked to a very small amount of radioactivity that allows doctors to see how organs function. When AldoView is injected, it highlights adrenal gland activity on a PET/CT scan.

The aim of the study is to find out whether AldoView can more accurately identify which adrenal gland is overactive, helping doctors decide whether surgery will be of benefit to the patient. Early research in 17 patients showed good results, good tolerability and no significant side effects. If successful, AldoView may provide a faster, safer, more accurate way to diagnose PA and guide treatment.

Who can participate?

We will recruit individuals aged 18 years and over from three groups: 1) patients with PA, 2)

patients with other adrenal conditions without PA, and 3) patients without adrenal conditions and without PA (i.e., healthy volunteers). Patients with PA should be willing and able to undergo adrenalectomy.

What does the study involve?
Following confirmation of eligibility, participants will attend the imaging department at an NHS centre with expertise in medical imaging. They will receive an injection of AldoView and undergo a PET/CT scan. Standard blood tests will be performed before the scan and repeated afterwards. Participants will be able to go home shortly after the scan, and all participants will receive a safety follow-up telephone call a few days after the scan to monitor for any side effects. For participants undergoing adrenalectomy as part of their routine care, surgically removed adrenal tissue will be included in the study analysis to confirm the PET/CT scan findings. Their follow-up data will be used to assess treatment response.

What are the possible benefits and risks of participating?
There is no direct personal benefit promised from participation in this study; however, the findings may help improve how primary aldosteronism (PA) is diagnosed and treated in the future. If the PET/CT scan identifies any new or unexpected findings, these will be discussed with the participant's usual clinical team. For the PA patients with inconclusive AVS, AldoView results will be shared with the local clinical team to help with shared decision-making for future management.
All medicines and radiotracers can occasionally cause unwanted effects, and not all possible side effects may be known. Participants will be closely monitored before, during, and after the scan. PET-CT scans are widely used and are generally considered very safe. The scan can be stopped at any time if the participant feels uncomfortable or wishes to withdraw.
Some participants may experience the following effects, which are usually mild and short-lived:
1. Mild discomfort or bruising at the injection site (where the study radiotracer is administered)
2. Temporary light-headedness after lying flat during the scan
Taking part in this study means that participants will have a PET/CT scan which they would not normally have. PET/CT scans use ionising radiation to form medical images. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

Where is the study run from?
University College London Hospitals Foundation Trust (UCLH) (UK)

When is the study starting and how long is it expected to run for?
May 2026 to May 2029

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

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

Contact information

Type(s)
Public

Contact name
Mr Andrew Tunstell

Contact details
University College London
London
United Kingdom
NW1 2PG
-
a.tunstell@ucl.ac.uk

Type(s)
Principal investigator

Contact name
Prof Bryan Williams

Contact details
University College London, Institute of Cardiovascular Science, Gower Street
London
United Kingdom
WC1E 6BT
-
bryan.williams@ucl.ac.uk

Type(s)
Scientific

Contact name
Prof Erik Arstad

Contact details
University College London, Kathleen Londsdale Building, 5 Gower Place
London
United Kingdom
WC1E 6BS
-
e.arstad@ucl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
1013308

Central Portfolio Management System (CPMS)
59363

Sponsor's protocol code number
162320

Study information

Scientific Title
An open-label, single-dose, multi-site, Phase IIb trial to assess the imaging performance of [18F] AldoView positron emission tomography (PET) in participants with and without primary aldosteronism

Acronym
IDEAL2

Study objectives
1. To evaluate how accurately [18F]AldoView PET-CT identifies aldosterone-producing adrenal tissue by comparing PET imaging findings with definitive histopathological confirmation (CYP11B2 immunohistochemistry) following adrenalectomy in participants with primary aldosteronism.
2. To investigate how safe [18F]AldoView is and how well people tolerate a single dose. This will be done by monitoring any side effects from the time the injection is given until the safety follow-up phone call.
3. To estimate the diagnostic accuracy of [18F]AldoView PET-CT for detecting primary aldosteronism. The scan results will be compared with the final medical diagnosis to see how often the scan gives the correct result.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)
Diagnostic, Efficacy, Safety, Other

Health condition(s) or problem(s) studied
Primary aldosteronism

Interventions
All participants receive a single intravenous bolus injection of [18F]AldoView as a sterile injectable solution at a dose of 200±20MBq (up to and including 10 micrograms nonradioactive compound).

The trial is openlabel and reviewerblind with two groups: a disease group of individuals with suspected primary aldosteronism undergoing standardofcare diagnostic evaluation and subtyping, and a control group of individuals with and without adrenal disorders (excluding primary aldosteronism). All participants undergo PETCT imaging after [18F]AldoView administration according to the protocoldefined schedule. For participants with primary aldosteronism and controls with other adrenal disorders, adverse events are monitored from administration of [18F]AldoView on Day 1 until a safety followup call on Day 4–8, and surgical outcomes in the primary aldosteronism group are assessed at 6 and 12 months post-

adrenalectomy. For control participants without adrenal disorders, adverse events are monitored from screening until the safety followup call on Day 4–8. No randomisation procedure is used, as this is a singledose, noncomparative imaging study in which all participants receive the same investigational medicinal product.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
[18F]AldoView [1-Cyclopropyl-5,6-difluoro-2-(5-[18F]fluoro)pyridin-3-yl)-1H-benzo[d]imidazole]

Primary outcome(s)
Correct Localisation Rate (CLR), defined as the proportion of participants with correct localisation of the affected adrenal gland, determined by concordance between [18F]AldoView PET-CT findings and post-surgical CYP11B2 immunohistochemical (IHC) staining. [18F]AldoView PET-CT is performed on Day 1 and interpreted by blinded readers, and results are compared with CYP11B2 IHC staining of resected adrenal tissue obtained at adrenalectomy (reference standard). CLR is assessed once both PET-CT and IHC results are available for each participant, with final analysis conducted at study completion in participants with evaluable PET-CT and conclusive IHC results.

Key secondary outcome(s))
1. The safety and tolerability of a single intravenous dose of [18F]AldoView, assessed by the incidence of treatment-emergent adverse events (TEAEs). The variable measured is the occurrence of one or more TEAEs. TEAEs are recorded from the time of intravenous administration of [18F]AldoView until completion of the scheduled safety follow-up call conducted between Day 4 and Day 8 post-dose.
2. The diagnostic accuracy of [18F]AldoView PET-CT for detecting primary aldosteronism (PA). The variables measured are positive percent agreement and negative percent agreement of [18F]AldoView PET-CT relative to the reference diagnosis of PA (PA-positive or PA-negative). PET-CT imaging is performed on Day 1 and interpreted by blinded readers, and results are compared with the reference diagnosis. Diagnostic accuracy is assessed once both PET-CT and reference diagnostic results are available for each participant, with final analysis conducted at study completion.

Exploratory outcomes:
1. The ability of [18F]AldoView PET-CT to predict the outcome of adrenalectomy in participants with PA. The variables measured are the sensitivity and specificity of PET-CT for predicting biochemical and clinical cure. PET-CT scans performed on Day 1 are interpreted by the trial multidisciplinary team (MDT), and findings are compared with post-operative outcomes classified according to the Primary Aldosteronism Surgical Outcome (PASO) criteria. Postoperative biochemical and clinical outcomes are assessed according to PASO at the scheduled post-surgical follow-up visits (6 and 12 months), and predictive accuracy is determined once both PET-CT interpretations and PASO-defined outcomes are available for each participant, with final analysis conducted at study completion.
2. The biodistribution and radiation dosimetry of [18F]AldoView. The variable measured is the effective radiation dose (mSv per MBq administered). Dosimetry is derived from whole-body PET-CT scans performed in four participants from the IDEAL1 First-in-Human study and four

additional participants enrolled in the IDEAL2 dosimetry sub-study. The effective dose is calculated based on the distribution of radioactivity in organs and tissues over time, with correction for urinary excretion. Dosimetry analysis is conducted after completion of the required whole-body imaging and associated radioactivity measurements for each participant.
3. The impact of [18F]AldoView PET-CT on patient management. The variable measured is the proportion of participants with a change in initial treatment intent based on standard of care (SoC). Initial treatment intent is documented prior to [18F]AldoView PET-CT, and any change in management plan is recorded after PET-CT results are reviewed and shared with the treating clinical team. The outcome is assessed by comparing pre-scan and post-scan treatment intent for each participant, with final analysis conducted at study completion.
4. The inter-reader performance and agreement for [18F]AldoView PET-CT interpretation. The variables measured are: (1) the diagnostic performance of each blinded reader compared with the reference standard (standard of truth) and (2) the level of agreement and discordance between blinded readers. PET-CT scans performed on Day 1 are independently interpreted by blinded readers, and their assessments are compared with the reference standard once available. Inter-reader agreement and individual reader performance are analysed after both PET-CT interpretations and reference standard results are available for each participant, with final analysis conducted at study completion.
5. The correlation between [18F]AldoView PET-CT findings, adrenal somatic mutations, demographics, and surgical outcomes. The variables measured include: (1) the presence and characteristics of lesions detected by [18F]AldoView PET-CT, (2) somatic mutations identified in surgically resected adrenal tissue, (3) participant demographic characteristics, and (4) post-surgical outcomes. Somatic mutation analysis is performed on resected adrenal tissue in participants who undergo adrenalectomy and have genetic testing available. Associations between PET-CT findings and mutation status, as well as correlations between demographics, mutation status, and surgical outcomes, are analysed once imaging, histological/genetic, and outcome data are available, with final analysis conducted at study completion.
6. The cost and cost-effectiveness of [18F]AldoView PET-CT compared with the current SoC diagnostic pathway. The variables measured include healthcare resource utilisation and associated costs of the diagnostic pathway, as well as long-term cost-effectiveness outcomes. Resource use and cost data are collected throughout the trial, and an economic evaluation comparing [18F]AldoView PET-CT with current SoC is conducted at the conclusion of the study, once all relevant clinical and imaging data have been collected.
7. The correlation between quantitative [18F]AldoView PET parameters and SoC diagnostic and surgical outcomes in PA. The variables measured include quantitative PET metrics (e.g., adrenal tracer uptake and adrenal standardised uptake value [SUV]), biochemical diagnosis of PA, adrenal vein sampling (AVS) lateralisation results, cortisol co-secretion status, and surgical outcomes. PET-CT scans are performed on Day 1 and reported by the trial multidisciplinary team (MDT) upon completion. Biochemical diagnosis of PA is recorded at enrolment; AVS lateralisation and cortisol co-secretion are recorded upon completion of SoC diagnostic testing; and surgical outcomes are assessed 6–12 months after adrenalectomy when biochemical and clinical follow-up data become available. Correlations between quantitative PET parameters and these outcomes are analysed once relevant paired data are available, and optimal threshold values for PET metrics are derived using receiver operating characteristic (ROC) curve analysis or other appropriate methods to maximise diagnostic accuracy.
8. The feasibility of determining the Correct Localisation Rate (CLR) at the lesion level. The variables measured are: (1) the proportion of PET-positive adrenal lesions for which lesion-level CLR can be determined through trial team assessment of lesion location and correlation with CYP11B2-positive features on pathology (i.e., adequate lesion matching is feasible), and (2) a descriptive estimate of lesion-level CLR within this subset. Lesion location on [18F]AldoView PET-CT is compared with CYP11B2 immunohistochemical (IHC) findings from resected adrenal tissue in surgically treated participants with primary aldosteronism. Analysis is performed once both

PET imaging data and corresponding lesion-level CYP11B2 IHC results are available for all participants undergoing adrenalectomy.

Completion date
01/05/2029

Eligibility

Key inclusion criteria
General criteria (all participants):
1. Age ≥18 years at the time of consent.
2. Able and willing to give informed consent, including literate and sufficiently fluent in English to understand written and verbal information about the trial.
3. Women of childbearing potential must agree to use a highly effective method of contraception from consent until completion of the safety follow-up call (Day 4–8 post-dose).
4. Male participants should use condoms during the study and for at least 8 days after dosing unless otherwise justified.
Willing and able to comply with all trial procedures, including PET-CT imaging, safety assessments, and follow-up as required.

Primary aldosteronism group:
1. Confirmed diagnosis of primary aldosteronism, established according to Endocrine Society-aligned standard-of-care diagnostic criteria, including:
1.1. Suppressed renin with inappropriately elevated aldosterone and/or elevated aldosterone-to-renin ratio, with confirmatory testing where required.
1.2. Participants undergoing standard-of-care diagnostic evaluation and subtyping for primary aldosteronism, including:
1.2.1. AVS performed within the previous 3 years or scheduled as part of standard clinical care, or
1.2.2. Eligibility for exemption from AVS according to recognised clinical guidelines (e.g., younger patients with clear unilateral disease on imaging).
2. Participants considered potential candidates for surgical or medical management of primary aldosteronism as part of routine clinical care.
3. Willingness to allow access to relevant medical records, including biochemical results, imaging, AVS findings, operative reports, and followup outcome data.
4. For participants undergoing adrenalectomy as part of standard care, willingness to allow use of resected adrenal tissue for histopathological and immunohistochemical assessment (CYP11B2 staining), which is essential for the primary endpoint.

Control groups (PA-negative):
1. Healthy volunteers with no evidence of primary aldosteronism or significant adrenal disease, confirmed by screening assessments.
2. Participants with adrenal disorders other than primary aldosteronism, in whom PA has been excluded by normal aldosterone and renin testing as part of standard care.
3. Control participants must not have biochemical or clinical evidence of primary aldosteronism at the time of enrolment.
4. WOCP must be willing to use a highly effective contraception.

Healthy volunteers allowed
Yes

Age group

Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to provide written informed consent
2. Allergy to contrast agents
3. Current use of aldosterone synthase inhibitor
4. Severe renal and hepatic failure
5. Unwilling to use effective contraception until safety follow-up

Date of first enrolment
31/05/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

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

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