

11C- metomidate positron emission tomography (PET) scanning for Conn's syndrome

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/06/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Timothy J. Burton

Contact details
Clinical Pharmacology Unit
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

Protocol serial number
6936

Study information

Scientific Title
Hypertension due to Conn's adenoma - the localisation of adrenal cortical adenomas by 11C-metomidate PET scanning following dexamethasone and fludrocortisone suppression

Study objectives

In order to ensure appropriate treatment, it is important to be able to identify Conn's adenoma reliably from other adrenal conditions. Current identification techniques, such as adrenal venous sampling, are time consuming, often invasive and problematic making treatment decisions difficult. It is proposed that non-invasive PET/CT scanning using ¹¹C-metomidate as a radiomarker will identify people with Conn's adenoma as well as currently used invasive techniques.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=6936>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 4 Research Ethics Board, 12/05/2008, ref: 08/H0305/20

Study design

Single-centre non-randomised treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Metabolic and Endocrine; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes)

Interventions

In addition to standard investigations for suspected Conn's adenoma, each participant will undergo a positron emission tomography (PET)/computed tomography (CT) scan with intravenous ¹¹C-metomidate (500 MBq) as a radio-label. The first 6 participants will undergo 3 scans to evaluate which suppression protocol produces the clearest image:

1. Without any additional drug therapies
2. Oral 0.5 mg dexamethosone 6-hourly for 48 hours prior to scan
3. Oral 0.5 mg dexamethosone 6-hourly for 48 hours prior to scan with the addition of 400 µg of fludrocortisone for 3 days prior to the scan

Intervention Type

Other

Phase

Phase IV

Primary outcome(s)

The sensitivity of ¹¹C-metamidate PET/CT scanning for detecting Conn's adenoma

Key secondary outcome(s)

1. The specificity of 11C-metomidate PET/CT scanning for detecting Conn's Syndrome
2. To determine the suppression protocol that leads to the best sensitivity of 11C-metomidate PET/CT scanning for detecting Conn's Syndrome

Completion date

30/04/2012

Eligibility

Key inclusion criteria

1. Male or female
2. Aged 18 years or over
3. Suspected Conn's syndrome or suspected adrenal hyperplasia or healthy with non-functional adenoma

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Inability to give informed consent
2. Heart failure
3. Women of childbearing potential not using contraception
4. Pregnant or breast feeding women

Date of first enrolment

17/04/2009

Date of final enrolment

30/04/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
<https://ror.org/04v54gj93>

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No