ISRCTN58267591 https://doi.org/10.1186/ISRCTN58267591

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

Submission date	Recruitment status
12/05/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
02/06/2015	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 probematic 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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
17/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 50

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
England

United Kingdom

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

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrooke's Hospital
Box 277, Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/research_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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