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**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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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 hypothesis
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

## Condition
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

### Overall study end date
30/04/2012

## Eligibility

### Participant 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

### Participant 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

### Recruitment start date
17/04/2009

### Recruitment end date
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 |