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# A randomised controlled study to evaluate the pelvi-calyceal anatomy of the kidney using three-dimensional multi-detector row CT (MDCT) imaging in patients before undergoing percutaneous renal intervention.

**Submission date**
30/09/2005

**Recruitment status**
No longer recruiting

**Registration date**
30/09/2005

**Overall study status**
Completed

**Last Edited**
14/09/2012

**Condition category**
Surgery

[_] 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

**Contact name**
Mr Khurshid Ridwan Ghani

**Contact details**
Urology Research Department
1st Floor, Ingleby House
St Georges Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT
+44 (0)20 8725 0271
Khurshid.ghani@stgeorges.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N0236151199

# Study information

### Scientific Title

### Study objectives
To evaluate the use of 3-dimensional multi-detector row computerised tomography (3D MDCT) in the treatment of renal pelvi-calyceal disease. The primary objective is to determine whether 3D MDCT is a valid and reliable pre-operative planning tool for endourological and percutaneous access to the collecting system of the kidney. The secondary objective is to assess whether pre-operative 'virtual endoscopy' performed using the 3D data, aids endourological removal of the calyceal stone.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Surgery: Renal

### Interventions
Research investigating the application of 3D imaging in endourolgy is in its infancy. To gain percutaneous access to the kidney and perform subsequent renoscopy in order to remove renal stones for example, the urologist and uroradiologist must have excellent 3D spatial awareness.

Currently patients have 2D images taken pre-operatively. Interventionalists use this data to mentally reconstruct a 3D image of the internal calyceal anatomy. Understanding the anatomy is key to a successful intervention. What would be of value is a reliable and valid imaging tool that is able to reconstruct in 3D the calyceal anatomy pre-operatively, and aid endourolgical intervention. Normally patients with complex renal stones requiring surgery have IVU's and CT's taken preoperatively at SGH. We aim to obtain out-patient multi-slice CT scans on patients who fit our inclusion criteria, and who will be undergoing percutaneous intervention in the future. The CT scans will be done as an outpatient investigation at the CT scan department of Princess Grace Hospital (the cost of which will be met by PGH administration). 3D CT will allow reconstruction of the fine ramifications of intracalyceal anatomy. It is our hypothesis that with this data, 3D volume reconstruction will help in pre-operative planning, it will allow us to determine best route of access as well as allowing virtual endoscopy to be done prior to the procedure. It is hoped this will have beneficial outcomes in terms of operative ability and morbidity.

### Intervention Type
Procedure/Surgery

### Phase
Not Specified

### Primary outcome measure
Reduced time to retrieve target calyceal calculus compared to control.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/05/2003

### Completion date
30/09/2005

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
20

### Key exclusion criteria
1. Patients > 30 stone
2. Pregnant women
3. Patients with severe learning difficulties
4. Patients with acute mental illness

### Date of first enrolment
01/05/2003

### Date of final enrolment
30/09/2005

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Urology Research Department**
London
United Kingdom
SW17 0QT

## Sponsor information

### Organisation
Department of Health

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

### Funder type
Government

### Funder Name
St George's Healthcare NHS Trust (UK) NHS R&D Support Funding

# 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 | 01/05/2009 | | Yes | No |