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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	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2012	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)
Not Specified

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(s)
Reduced time to retrieve target calyceal calculus compared to control.

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/09/2005

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Urology Research Department
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

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	01/05/2009		Yes	No