ISRCTN67807054 https://doi.org/10.1186/ISRCTN67807054

Prospective randomised trial of tubeless vs conventional percutaneous nephrolithotomy (PCNL)

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 12/04/2011	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Sudhanshu Chitale

Contact details
Department of Urology
Norfolk and Norwich University Hospital NHS Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY
+44
sudhanshu.chitale@nnuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0547147994

Study information

Scientific Title

Study objectives
Is performing percutaneous renal surgery without leaving a tube drain in the kidney postoperatively as safe as with the placement of a postop drain? Our hypothesis is that, in selected cases, it is not only as safe but also associated with reduced postoperative morbidity and hospital stay.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Comparison of two different approaches to keyhole surgery of the kidney with stone disease.

Added 26 August 2008: trial stopped due to poor recruitment and lack of funding.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Postoperatve blood loss, postoperative incidence of infection and urinary leak (urinoma).

Secondary outcome measures
Analgesic requirement, hospital stay, readmission rates.

Overall study start date
01/09/2003

Completion date
01/09/2005

Reason abandoned (if study stopped)
Lack of funding & poor recruitment

Eligibility

Key inclusion criteria
Adults with small-moderate size pelvicalyceal stones.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
115 in each arm = 230

Key exclusion criteria
Patients with complete stones, solitary functioning kidney, renal insufficiency

Date of first enrolment
01/09/2003

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Urology
Norwich
United Kingdom
NR4 7UY

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
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT (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