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

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

# 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

# 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

Postoperative 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