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PUrE: percutaneous nephrolithotomy, flexible ureterorenoscopy and extracorporeal shockwave lithotripsy for lower pole kidney stones

Submission date
11/11/2015

Recruitment status
No longer recruiting

Registration date
11/11/2015

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Kidney stones are stone-like lumps that can develop in one or both of the kidneys. Although some stones do not cause pain or discomfort, patients can develop serious pain, infection, blood in urine, kidney problems or even kidney failure. Many stones occur in the lower part of the kidney (lower pole stones). These stones are more likely to require treatment because they are less likely to pass on their own. Currently within the NHS there are three treatment options for lower kidney stones: extracorporeal shockwave lithotripsy (ESWL), percutaneous nephrolithotomy (PNL), and flexible ureterorenoscopy with laser lithotripsy (FURS). We are uncertain which of these treatments is best at getting rid of stones and which is best value for patients and the NHS. They each have advantages and disadvantages (benefits and harms). The aim of this study is to determine the clinical effectiveness and cost effectiveness of these three treatment options for lower kidney stones.

Who can participate?
Patients aged 16 or over with lower pole kidney stones.

What does the study involve?
Patients with smaller stones are randomly allocated to be treated with either FURS or ESWL. Patients with larger stones are randomly allocated to be treated with either FURS or PCNL. In FURS, a small telescope is passed into the bladder through the urethra and up to the kidney, and a laser beam breaks the stone into pieces, which are then either retrieved or the passed spontaneously after the procedure. In ESWL, shockwaves from a machine outside the body target and break the stone into pieces, which are then passed spontaneously. In PCNL, a hole is made in the skin, a tube is inserted through it into the kidney, and a small telescope is inserted into the kidney via the tube to break the stone and remove all the pieces.

What are the possible benefits and risks of participating?
Patients undergoing FURS require an anaesthetic and sometimes a hospital stay, and there is a

small risk of complications (e.g., infection, bleeding). ESWL does not need an anaesthetic nor hospital stay, but passing the pieces can take time, more than one treatment may be needed for larger stones, and some pieces may not pass at all. PCNL usually clears the stone completely in one go, but needs an anaesthetic, hospital stay, and may cause more serious problems (bleeding and infection). We think FURS may clear the stone more efficiently than ESWL, but less well than PNL.

Where is the study run from?
Aberdeen Royal Infirmary (UK) and 48 hospitals across the UK (as of 29/10/2018)

When is the study starting and how long is it expected to run for?
May 2015 to February 2023

Who is funding the study?
National Institute for Health Research Technology Assessment Programme (NIHR HTA) (UK).

Who is the main contact?
Dawn McRae, pure@abdn.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/PUrE/

Contact information

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Additional identifiers

EudraCT/CTIS number
2014-002751-25

IRAS number
188563

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA 13/152/02, IRAS 188563

Study information

Scientific Title
The clinical and cost effectiveness of surgical interventions for stones in the lower pole of the kidney: the percutaneous nephrolithotomy, flexible ureterorenoscopy and extracorporeal lithotripsy for lower pole kidney stones randomised controlled trial (PUrE RCT)

Acronym
PUrE

Study objectives
The null hypotheses being tested are:
1. The use of flexible urterorenoscopy with laser lithotripsy (FURS) to treat lower pole kidney stones less than 10 mm will not be superior to extracorporeal shockwave lithotripsy (ESWL) as assessed by a relative increase of at least 0.3 of a standard deviation (SD) on the EQ-5D AUC up to 12 weeks post treatment
2. The use of FURS to treat lower pole stones of the kidney 10 mm or greater and less than or equal to 25 mm will not be superior to percutaneous nephrolithotomy (PCNL) by an increase of 0.3SD on the EQ-5D AUC up to 12 weeks post treatment.

Further information can be found at: http://www.nets.nihr.ac.uk/projects/hta/1315202

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 10/11/2015, REC ref: 15/NS/0113

Study design

Two separate pragmatic multicentre patient-randomised open-label superiority randomised controlled trials with an initial internal pilot phase

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Health condition(s) or problem(s) studied
Lower pole kidney stones

Interventions
RCT 1: FURS versus ESWL for stone sizes <=10 mm
RCT 2: FURS versus PCNL for stone sizes >10mm <=25 mm

FURS
A flexible ureteroscope is passed into the kidney and a holmium laser fibre used to fragment stones. Stone fragments are then either retrieved or the patient passes them spontaneously after the procedure.

PCNL
A small incision is made in the skin through which a tube is inserted into the kidney. A nephroscope is inserted via this tube to retrieve the stone, or fragment it before retrieval. The intention is to remove all stone fragments.

ESWL
An external acoustic pulse (shockwave), from outside the body is focused onto the kidney stone, causing it to fragment. Stone fragments are then passed spontaneously by the patient in the days following the treatment. It may be delivered by fixed (static, on-site) or mobile (external) machines.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Patient-reported: Health status (EQ-5D-5L) area under the curve (AUC) to 12 weeks post intervention, based upon EQ-5D completion at fixed time points; at baseline (recruitment), just prior to initial intervention (FURS, PCNL or first session of ESWL), at 1, 2, 4, 8, and 12 weeks after initial intervention, and at variable time points; just prior and 1 week after any additional

intervention (including planned additional ESWL sessions and removal of stent) and once during hospitalisation for adverse events related to treatment (e.g. pain and infection).
2. Economic: Incremental cost per quality adjusted life year (QALYs) gained at 12 months post-randomisation based on the estimated NHS costs and participant responses to the EQ-5D (including additional time point at 12 months).

Secondary outcome measures
1. Patient reported:
1.1. Severity of pain as measured by the Numeric Rating scale (NRS; completed with EQ-5D-5L)
1.2. Generic health profile as measured by the SF-12 (completed at baseline and 12 months)
1.3. Use of analgesia (completed with NRS and EQ-5D)
2. Clinical:
2.1. Stone clearance measured at between 8 and 12 weeks post initial intervention using renal imaging (CTKUB preferred but plain x-ray and ultrasound acceptable). Measured by local trial staff and categorized as complete, acceptable, or unacceptable. Also maximum dimension of the largest fragment of the treated stone in mm
2.2. Need for additional treatment (carried out or planned) at 12 weeks post-initial treatment and 12 months post randomisation
2.3. Complications during initial intervention. Intervention-related complications at 12 weeks (categorised by Clavien-Dindo classification) post treatment and up to 12 months post randomisation. All measured by site staff and entered on CRF.
3. Economic:
3.1. NHS primary and secondary care resources used and their costs
3.2. Patient costs (out of pocket), time off work up to 12 months post randomisation
Data gathered from completion of CRFs by site staff and participant questionnaire at 12 weeks post initial treatment and 12 months post randomisation.

Overall study start date
01/12/2015

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Adults ≥16 years of age
2. Lower pole stone ≤25 mm in maximum dimension with decision to treat that stone
3. Presence of stone confirmed by CTKUB
4. Able and willing to undergo either treatment for specified stone size
5. Capacity to give informed consent to participate in trial which includes adherence to trial requirements

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1044 (522 in each RCT)

Total final enrolment
625

Key exclusion criteria
1. Pregnancy
2. Patients with co-existing stone that takes precedence in deciding treatment modality (such as obstructing ureteric stone or large upper pole stone)
3. Patients with health or other factors that are absolute contraindications to an intervention that they may be allocated
4. Patients unable to understand or complete trial documentation

Date of first enrolment
01/05/2015

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Technology Assessment Programme (NIHR HTA)

Results and Publications

Publication and dissemination plan

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/06/2020	08/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		13/03/2025	27/05/2025	Yes	No
Results article		22/04/2025	27/05/2025	Yes	No