

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

<b>Submission date</b> 11/11/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/08/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> 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

## Contact information

### Type(s)

Scientific

### Contact name

Prof Samuel McClinton

### Contact details

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2014-002751-25

**Integrated Research Application System (IRAS)**  
188563

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Lower pole kidney stones

### Interventions

RCT 1: FURS versus ESWL for stone sizes  $\leq 10$  mm

RCT 2: FURS versus PCNL for stone sizes  $>10\text{mm} \leq 25$  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(s)

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).

### Key secondary outcome(s)

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.

## **Completion date**

28/02/2023

# **Eligibility**

## **Key inclusion criteria**

1. Adults  $\geq 16$  years of age

2. Lower pole stone  $\leq 25$  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

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Sex**

All

## **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**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre****Aberdeen Royal Infirmary**

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**Study participating centre****Pinderfields Hospital**

Aberford Road

Wakefield

United Kingdom

WF1 4DG

**Study participating centre****Freeman Hospital**

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Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Addenbrooke's Hospital**  
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Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
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Chelmsford  
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CM1 7ET

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Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**  
**Southampton General Hospital**  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**Southmead Hospital**  
Dorian Way  
Westbury-on-Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**  
**Churchill Hospital**  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LE

**Study participating centre**  
**Charing Cross Hospital**  
Fulham Palace Road  
London  
United Kingdom  
W6 8RF

**Study participating centre**  
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IV2 3UJ

**Study participating centre**  
**Arrowe Park Hospital**  
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Birkenhead  
Wirral  
United Kingdom  
CH49 5PE

**Study participating centre**  
**James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**



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Sheffield  
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S10 2JF

**Study participating centre**  
**Royal Oldham Hospital**  
Rochdale Road  
Manchester  
United Kingdom  
OL1 2JH

**Study participating centre**  
**Belfast City Hospital**  
Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre**  
**Wrexham Maelor Hospital**  
Croesnewydd Road  
Wrexham  
United Kingdom  
LL13 7TD

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**St James's University Hospital**  
Beckett Street  
Leeds  
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LS9 7TF

**Study participating centre**  
**Manchester Royal Infirmary**  
Grafton Street  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Salford Royal Hospital**  
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Salford  
United Kingdom  
M6 8HD

**Study participating centre**  
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Bournemouth  
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BH7 7DW

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United Kingdom  
SR4 7TP

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United Kingdom  
KT2 7QB

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**Wythenshawe Hospital**  
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Manchester  
United Kingdom  
M23 9LT

**Study participating centre**  
**Stockport NHS Foundation Trust**  
Stepping Hill Hospital  
Poplar Grove  
Hazel Grove  
Stockport  
United Kingdom  
SK2 7JE

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**Eastbourne District General Hospital**  
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PR8 6PN

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CT1 3NG

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L35 5DR

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L14 3LB

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United Kingdom  
KT18 7EG

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Cheltenham  
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Bradford  
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**Blackpool Teaching Hospitals NHS Foundation Trust**  
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Blackpool Victoria Hospital  
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## **Sponsor information**

**Organisation**  
University of Aberdeen (UK)

**Organisation**  
Grampian Health Board (UK)

## **Funder(s)**

**Funder type**

Government

Funder Name

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

Results and Publications

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?
<a href="#">Results article</a>	protocol	22/04/2025	27/05/2025	Yes	No
<a href="#">Results article</a>		01/08/2025	19/08/2025	Yes	No
<a href="#">Protocol article</a>		04/06/2020	08/06/2020	Yes	No
<a href="#">HRA research summary</a>	Participant information sheet		28/06/2023	No	No
<a href="#">Other publications</a>		13/03/2025	27/05/2025	Yes	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes