

Therapeutic interventions for stones of the ureter

Submission date 07/02/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 21/02/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/03/2022	Condition category Urological and Genital Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Ureteric stones (kidney stone) are very common and painful; 2-3% of the general population (1.8 million in the UK) have suffered from this condition. Ureteric stones can pass in their own time and some patients only require initial treatment with pain killers and, if appropriate, anti-sickness medication and drugs which relax the muscle fibres of the ureter. In some cases the treatments described above do not work or patients are not suitable for such care and further routine intervention (stone removal) is required. This study is investigating two methods used to remove stones: extracorporeal shockwave lithotripsy (ESWL), which is a shockwave treatment applied from the outside of the body, and ureteroscopic stone treatment, a telescopic procedure to remove the stone.

Who can participate?

Patients aged 16 or older who have a single ureteric stone in the ureter

What does the study involve?

Participants are randomly allocated to be treated with either ESWL or ureteroscopy. All participants are followed up for a period of six months. Participants complete questionnaires about their general health, pain and use of painkillers at the time they join the study, directly before their treatment and again one week after the procedure. At about 8 weeks and 6 months after joining the trial participants complete further questionnaires. In addition, following their ureteric stone treatment, participants return to an outpatient clinic at their recruiting hospital to check how they are getting on. If their symptoms are still not adequately controlled they may receive further treatment as necessary.

What are the possible benefits and risks of participating?

There may be no direct benefit to patients who take part, but they will be helping doctors to assess which treatment is best and safest.

Where is the study run from?

The study is co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT) and is co-sponsored by the University of Aberdeen and NHS Grampian (UK)

When is the study starting and how long is it expected to run for?

March 2013 to February 2017

Who is funding the study?

NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA) (UK)

Who is the main contact?

Prof. S McClinton

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

HTA 10/137/01, 3/087/12

Study information

Scientific Title

A multicentre randomised controlled trial of extracorporeal shockwave lithotripsy, as first treatment option, compared with direct progression to ureteroscopic treatment, for ureteric stones

Acronym

TISU

Study objectives

The hypothesis being tested is that outcome in patients receiving extracorporeal shockwave lithotripsy (ESWL) as their first treatment option is not inferior to outcome in patients receiving direct ureteroscopic retrieval.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committees - North of Scotland, 15/02/2013, ref: 13/NS/0002

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ureteric stone treatment

Interventions

Participants will be randomly allocated to either ESWL or ureteroscopy.

Extracorporeal shockwave lithotripsy (ESWL) involves generation of a shock-wave, external to the body, focused on the stone, causing it to fragment with the fragments subsequently passing spontaneously. A variety of systems (differing means of generating shock-waves, different focusing mechanisms) are available. It is routinely performed in an outpatient setting with pain relief or sedation as required. Recruitment will occur only in established centres with fixed-site lithotripters. This will allow some standardisation of protocols on times to treatment and ESWL delivery. Up to two sessions of ESWL will be considered as one intervention as per standard practice.

Ureteroscopy is the use of small semi-rigid or flexible ureteroscopes, in conjunction with intracorporeal lithotripsy devices, such as the holmium laser, to directly visualise and fragment ureteric stones. Smaller stones, in the lower ureter, can often be removed intact using basketing devices. It is currently most often performed as a day-case procedure (but may require hospital admission depending on complexity) and usually requires general anaesthesia.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The study has a primary clinical and a primary economic outcome reflecting the multidimensional nature of the possible effects the intervention may have.

Clinical: Clearance of ureteric stones operationally defined as no further intervention required to facilitate stone clearance up to 6 months from randomisation.

Economic: Incremental cost per quality adjusted life years (QALYs) gained at 6 months from randomisation. QALYs are based on the responses to the EQ-5D.

Key secondary outcome(s)

Patient-reported, measured at pre and 1 week post intervention, 8 weeks and 6 months post randomisation:

1. Severity of pain measured by the Numeric Rating scale (NRS)
2. Generic health profile measured by the SF-12 (8 weeks and 6 months only)
3. Health status measured by the EQ5D
4. Use of analgesia
5. Acceptability of received procedure (8 weeks and 6 months only)

Clinical: Further interventions received, complications up to 6 months post randomisation

Economic: NHS primary and secondary care use and costs up to 6 months, patient costs; incremental cost per surgical interventions averted.

Completion date

28/02/2017

Eligibility**Key inclusion criteria**

1. Presence of stone confirmed by Computed Tomography Scan of the Kidneys, Ureters and Bladder (CTKUB)
2. Patients with a ureteric stone requiring removal
3. Adults ≥ 16 years of age
4. Single ureteric stone requiring treatment
5. Suitable for either ESWL or ureteroscopic treatment
6. Capable of giving written informed consent, which includes adherence with the requirements of the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

613

Key exclusion criteria

1. Pregnancy
2. Stones not confirmed by CTKUB
3. Bilateral ureteric stone(s)
4. Patients with abnormal urinary tract anatomy (such as a horseshoe kidney or ileal conduit)
5. Patients unable to understand or complete trial documentation

Date of first enrolment

01/03/2013

Date of final enrolment

28/02/2017

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Aberdeen Royal Infirmary

Aberdeen

United Kingdom

AB25 2ZB

Sponsor information

Organisation

University of Aberdeen

ROR

<https://ror.org/016476m91>

Organisation

NHS Grampian

ROR

<https://ror.org/00ma0mg56>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	sub study results	10/02/2021	22/02/2021	Yes	No
Results article		31/03/2021	21/02/2022	Yes	No
Results article		01/03/2022	21/03/2022	Yes	No
Protocol article	protocol	22/05/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	evaluation of recruitment processes	11/08/2017		Yes	No