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Therapeutic interventions for stones of the ureter

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised controlled trial

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 to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/03/2013

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

Age group
Adult

Sex
Both

Target number of participants
1000

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
Scotland

United Kingdom

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZB

Sponsor information

Organisation
University of Aberdeen

Sponsor details

Research and Innovation
University Office
Kings College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk/

ROR
https://ror.org/016476m91

Organisation
NHS Grampian

Sponsor details
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZN

Sponsor type
Hospital/treatment centre

Website
http://www.nhsgrampian.org/nhsgrampian/gra_display_home_2015.jsp?p_applic=CCC&p_service=Content.show&pContentID=9298&

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	evaluation of recruitment processes	11/08/2017		Yes	No
Protocol article	protocol	22/05/2018		Yes	No
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
HRA research summary			28/06/2023	No	No