ISRCTN95762080 https://doi.org/10.1186/ISRCTN95762080

Effect of voltage escalation and shock wave rate during stone treatment

Submission date	Recruitment status	[_] Prospectively registered
17/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2015	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Beat Roth

Contact details
Urology Department (Urologische Universitätsklinik)
Inselspital
Bern
Switzerland
3010

Additional identifiers

Protocol serial number
089/10

Study information

Scientific Title
Randomised, single blinded trial to compare immediate versus delayed voltage escalation and the effect of different shock wave rates during shock wave lithotripsy of single kidney or ureteral stones

Study objectives

In animal models delayed voltage escalation during shock wave lithotripsy of renal stones has been shown to be more effective, with a concurrent lower rate of renal damage (subcapsular or perirenal hematomas). These animal studies suggest that low-energy shock waves might provide a beneficial effect by priming the stones for fragmentation by the following higher energy waves. Therefore, a delayed voltage increase might be more effective for the stone fragmentation with concurrent lower energy dose and lower kidney damage.
For ureteral stones, energy adaptation did not show any beneficial effect. But as in kidney stones, a lower shock wave rate might have a beneficial impact. We therefore postulate, that shock wave frequency of 60 shocks per minute has a better outcome in ureteral stone patients than a shock wave rate of 90 shocks per minute and for renal calculi, a voltage escalation shock wave lithotripsy has a better outcome than a immediate voltage escalation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bern Ethics Committee (Ethikkommission Bern), May 2010, ref: 089/10

Study design
Single-centre prospective randomised controlled single-blind interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urinary stone treatment with shock wave lithotripsy

Interventions
Shock wave lithotripsy of ureteral and renal calculi. Duration of treatment is about 1h and there is only one single treatment per patient.
The follow up is done by ultrasound, blood samples, x-rays and urinary examination 1 day and three months after the intervention.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Stone disintegration/stone clearance after 3 months

Key secondary outcome(s))
1. Secondary treatments or interventions for the same stone
2. Perirenal/subcapsular hematomas
3. Complications according to the Dindo-Clavien system
4. Microalbumin and Beta-2 microglobulin measurement as a marker of renal damage (proximal tubulus/glomerular)
Outcomes will be measured at 1 day and 3 months after the intervention.

Completion date

31/12/2011

Eligibility

Key inclusion criteria
1. Patients with renal or ureteral stones scheduled for shock wave lithotripsy
2. Patients > 20 years of age
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. < 20y of age
3. Anticoagulation or aspirin medication
4. Urinary tract infection
5. Stones > 2cm (indication for Percutaneous Nephrolithotomy [PCNL] or Ureteroscopic stone treatment)

Date of first enrolment
01/07/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
Inselspital
Bern
Switzerland
3010

Sponsor information

Organisation
Inselspital, University Hospital Berne (Switzerland)

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Inselspital, University Hospital Berne (Switzerland) - Urology Department (Urologische Universitätsklinik)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No