

Effect of voltage escalation and shock wave rate during stone treatment

Submission date
17/06/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
06/07/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/06/2015

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet [in German]

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 measure

Stone disintegration/stone clearance after 3 months

Secondary outcome measures

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.

Overall study start date

01/07/2010

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

Age group

Adult

Sex

Both

Target number of participants

640

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)

Sponsor details

c/o Beat Roth

Urology Department (Urologische Universitätsklinik)

Bern

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3010

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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