ISRCTN12915426 https://doi.org/10.1186/ISRCTN12915426

To determine whether a low-dosage, digital X-ray scanning (LODOX-Statscan) can detect kidney stones in order to reduce radiation dosage

Submission date
13/11/2014

Recruitment status
No longer recruiting

Registration date
10/12/2014

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. We are carrying out a study of 30 patients presenting in the emergency department for kidney stones. We want to find out whether a technique of X-ray scanning requiring only about one-third of the radiation dose used for normal X-ray, called LODOX, can detect kidney stones. Our goal is to eventually reduce the radiation dosage needed for kidney stone detection and follow-up.

Who can participate?
Adults over 18, presenting in our emergency department for kidney stones.

What does the study involve?
Patients receive a LODOX-Statscan in our emergency department after the existence of kidney stones has been proved by computed tomography (CT) scan.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but if our study shows that kidney stones really can be found by LODOX-Statscan, in future a LODOX could replace the conventional radiography. This means that future patients will benefit from the lower radiation dosage of the LODOX. Radiation dosage is an issue because radiation is known for its potential of causing cancer. The main risk is the additional radiation dose of the LODOX. However, the dose is very small.

Where is the study run from?
The study has been set up by the Urology Department of the University of Bern (Switzerland).

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in November 2014. Participants will be enrolled on the study for a period of six months.

Who is funding the study?
University Clinic of Urology (Urologische Universitaetsklinik) (Switzerland).

Who is the main contact?
Dr Stefanie Hnilicka
urology.berne@insel.ch

Contact information

Type(s)
Scientific

Contact name
Dr Stefanie Hnilicka

Contact details
Anna-Seiler-Haus
Inselspital
Bern
Switzerland
3010

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A pilot study to evaluate if low-dosage, digital X-ray scanning (LODOX-Statscan) can detect ureteral stones

Acronym
N/A

Study objectives
It is hypothesised that ureteral stones are visible in low-dosage, digital X-ray scanning (LODOX-Statscan) and that stone detection with LODOX is superior compared to conventional radiography while requiring lower radiation dosage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Canton Bern, Switzerland, 11/2013, ref: 156/12

Study design
Pilot study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Kidney and ureteral stones/reducing radiation dosage

Interventions
CT scan in all patients. A low-dosage, digital X-ray scanning (LODOX-Statscan) requiring a radiation dose of about 80 µSv will be performed in all participants. Total duration of intervention: approximately 5 minutes.

Intervention Type
Other

Primary outcome(s)
Stone detection rate by LODOX

Key secondary outcome(s))
1. Reducing radiation dosage
2. Comparability of stone size measured in LODOX, CT and conventional radiography
3. Fine-tuning adjustment of LODOX

Completion date
20/05/2015

Eligibility

Key inclusion criteria
1. Patients with kidney or ureteral stones proved by computed tomography (CT)
2. > 18 years
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
41

Key exclusion criteria
1. Persistent, analgetic resistant pain
2. Pregnancy

Date of first enrolment
20/11/2014

Date of final enrolment
20/05/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Anna-Seiler-Haus
Bern
Switzerland
3010

Sponsor information

Organisation
University Clinic of Urology (Urologische Universitaetsklinik) (Switzerland)

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
University/education

Funder Name
University Clinic of Urology (Urologische Universitaetsklinik) (Switzerland)

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	01/04/2020	06/06/2019	Yes	No