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

Submission date 13/11/2014	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
		[_] Protocol	
Registration date 10/12/2014	<b>Overall study status</b> Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	[_] Individual participant data	
25/10/2020	orological and defiled Diseases		

### 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

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

**Secondary study design** Other

**Study setting(s)** Hospital

**Study type(s)** Diagnostic

Participant information sheet

### 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 measure** Stone detection rate by LODOX

#### Secondary outcome measures

- 1. Reducing radiation dosage
- 2. Comparability of stone size measured in LODOX, CT and conventional radiography
- 3. Fine-tuning adjustment of LODOX

Overall study start date

20/11/2014

**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

### Age group

Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 30

**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)

### Sponsor details

c/o Dr Stefanie Hnilicka Inselspital Bern Switzerland 3010

**Sponsor type** University/education

ROR https://ror.org/01q9sj412

### Funder(s)

**Funder type** University/education

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

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