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Novel multimodality imaging for the evaluation of obstructed urinary system in kidney stone disease patients.

Submission date
23/11/2023

Recruitment status
No longer recruiting

Registration date
03/01/2024

Overall study status
Completed

Last Edited
02/09/2024

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
Abdominal pain is a common reason people end up in the emergency room, and about 5% of these cases are due to kidney stone disease (KSD). This condition affects 13% of men and 7% of women, and if not treated properly, it can come back in 50% of cases within 5 years. In the United States, dealing with KSD costs around $5 billion each year, covering hospital stays, procedures to remove stones, and lost work hours.

Experts from the American Urological Association (AUA) and the American College of Radiology (ACR) recommend using CT scans as the first imaging test for these patients. However, while CT scans can identify the presence of kidney stones and certain signs of blockage, they don't directly show whether there's an obstruction, how well the kidneys are working, or the flow dynamics of urine. Instead, they rely on secondary signs like "fat stranding" or a dilated collection system to determine if there's a blockage, but these signs aren't very reliable, with only a 56% accuracy.

It's crucial to rule out obstruction quickly because kidney function can recover if treated promptly. If left untreated for weeks, though, obstruction can cause irreversible damage and potentially lead to chronic kidney failure. Outflow obstruction from the kidney can also cause other issues like chronic tubulointerstitial disease, bladder residual urine, chronic or recurring urinary tract infections, incontinence, and problems from long-term catheter use.

There's a common belief that stones smaller than 5 mm will pass through the urinary system on their own, but recent studies dispute this idea. Stones as small as 4 mm may not naturally be expelled. MAG3 scintigraphy, a test using 99mTc-MAG3, has been found to detect some degree of obstruction in up to 50% of cases with silent ureteral stones (stones without symptoms). This method, done with conventional gamma camera/scintigraphy, has a high positive predictive value (PPV) of 90.6% for diagnosing obstructive kidney disease.

Advanced equipment, like Digital SPECT/CT, can perform both a CT scan and a 99mTc-MAG3 digital scintigraphy simultaneously. Our research group, with previous experience in diagnostic

imaging and kidney stones, aims to build on this by using state-of-the-art equipment to further our understanding of these conditions.

Who can participate?
Adult patients with a confirmed kidney stone disease at CT.

What does the study involve?
We will perform a SPECT/CT study in a novel CZT camera as part of routine care.

What are the possible benefits and risks of participation?
The expected benefit is the detection and better characterization of obstruction secondary to kidney stone disease. The risk is would be increased pain during the study due to the use of a diuretical agent.

Where is the study run from?
Clinical Physiology Department, Nuclear Medicine Unit, Linköping University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2019 to March 2024

Who is funding the study?
Linköping University Hospital, Clinical Physiology Department (Sweden).

Who is the main contact?
Miguel Ochoa Figueroa, MD, PhD, miguel.ochoa.figueroa@regionostergotland.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Diagnostic performance of MAG-3 SPECT/CT in the detection of obstruction of the urinary system caused by kidney stone disease, comparison with stand alone CT.

Study objectives
The degree of functional and hydrodynamical stress exerted on the urinary tract in acute obstruction is in direct proportion to the degree of alterations in function, vascular distribution and cellular perinephric changes in the kidney and determines irreversible changes in its morphology and function. SPECT-CT 99mTc-MAG3 can lead to better diagnosis of kidney stone disease and obstruction of the urinary tract, which will lead to better patient care and optimization of resources.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/05/2019, Etiksprövningsmyndigheten (Box 2110, Uppsala, 75002, Sweden; +46104750800; registrator@etikprovning.se), ref: 2019-01608

Study design
Observational case series

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Kidney stone disease

Interventions
This is a study that included patients with kidney stone disease, confirmed by CT, who later accepted to be included in the study which consided in performing a SPECT/CT. The scintigraphy study is performed using a new digital cadmium zinc telluride (CZT) camera which has the ability to acquire 3D images SPECT/CT. Both studies are routinely performed in our centre and are well-established studies in these patients worldwide, although in different time points. The approach is to do both at the same time, in order to save time and resources, using a one-stop shop approach.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MAG-3 Nephromag, furosemid

Primary outcome(s)
Accuracy, sensitivity, specificity, positive predictive value and negative predictive value of the test using a digital CZT (cadmium-inctelluride) multimodality equipment SPECT-CT (single-photon emission computed tomographycomputed tomography) at one timepoint in patients with kidney stone disease to evaluate obstruction of the urinary system.

Key secondary outcome(s))
Accuracy, sensitivity, specificity, positive predictive value and negative predictive value of the test for the evaluation of obstruction of the urinary system using only data from CT, using data only from SPECT and its combination.

Completion date
15/03/2024

Eligibility

Key inclusion criteria
Adult patients who come to the emergency department due to renal colic and have kidney stone disease confirmed at the emergency CT.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
20

Key exclusion criteria
Under age (<18 years)

Date of first enrolment
23/02/2022

Date of final enrolment
15/01/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University Hospital
Universitetssjukhuset
Linköping
Sweden
58185

Sponsor information

Organisation
Fysiologiska Kliniken i Linköping

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Fysiologiska Kliniken, Linköping University Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request. Miguel Ochoa Figueroa, MD, PhD. miguel.ochoa.figueroa@regionostergotland.se. Consent from participants was required and obtained. The type of data that can be shared will depend on what is permitted by Swedish law.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/09/2024	02/09/2024	Yes	No
Participant information sheet			24/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes