Asymptomatic gout in patients with severe renal failure measured by Dual Energy CT (DECT) and Ultrasonography.

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to determine the percentage of patients with CKD, without a history of gout or attacks of arthritis, that have tophi measured by US,DECT and clinical examination. to determine the percentage of patients with CKD, that have tophi measured by US, and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON43979

Source
ToetsingOnline

Brief title
GoUT, Tophi, Renal failure (GUTTeR)

Condition

- Joint disorders
- Nephropathies

Synonym
Gout, tophi, urate deposits

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DECT, Gout, Renal failute, Ultrasonography

Outcome measures

Primary outcome

The percentage of patients with MSU deposits on

- Dual Energy CT-scan

- Ultrasound

- Physical examination

The percentage of patients with erosions on

- conventional x-ray

Secondary outcome

Difference between patient with MSU deposits on examination in:

- Quality of life measured by the HAQ and SF-36

- Uric acid levels in serum

Study description

Background summary

Gout is a metabolic disorder of purine metabolism with primary manifestations of acute and chronic arthritis , tophus formation and bone destruction. Gout is more common in patients with chronic kidney disease (CKD). Tophi and gout flares are associated with a lower quality of life and tophi can cause bone erosions and joint destruction. Tophi and subsequent bone erosions can occur without spells of arthritis (= asymptomatic gout). However data on the presence of tophi and erosion in asymptomatic patients with renal failure is lacking.
Our hypothesis is that these can be detect in these patients with the use of novel imaging techniques; dual energy computed tomography (DECT) and/or ultrasound (US). In the future patients can be treated before they have symptomatic gout and prevent the bone destruction by tophi leading to a decrease in quality of life. In addition we will investigate the presence of

erosions and tophi in all patients with CKD.

Study objective

to determine the percentage of patients with CKD, without a history of gout or attacks of arthritis, that have tophi measured by US,DECT and clinical examination.
to determine the percentage of patients with CKD, that have tophi measured by US, and clinical examination and or erosions measured by conventional x-ray.

Study design

Cross sectional cohort study

Study burden and risks

The burden consists of one extra 1,5 hour visit to the hospital in which 2 invasive investigations (Ultrasound and DECT scan/ x-ray) are performed. the risk associated with these investigations is neglectable.
Benefit is that the patients are thoroughly screened for a treatable comorbidity of renal failure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- eGFR <30 ml/min/1,73m2
- Chronic kidney disease (> 6months)
- 18 years or older

Exclusion criteria

- Poor knowledge of the Dutch language
- No written informed consent
- Pregnancy;
- Dialysis-dependency
Only for a selection of the patients:
- history of gout or history or attacks of arthritis
- Use of urate lowering drugs (iallopurinol, desuric and adenuric)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-08-2015
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53350.078.15