

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

Published: 05-08-2015

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	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 failure, 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 detected 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**

### **Public**

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### **Scientific**

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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/1,73m<sup>2</sup>
- 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