# Reade Gout cohort Cardiovascular risk & management in gout patients

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

# Summary

### ID

NL-OMON44794

**Source** ToetsingOnline

**Brief title** Cardiovascular risk management in gout

# Condition

- Joint disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym Gout

**Research involving** Human

# **Sponsors and support**

Primary sponsor: Jan van Breemen Instituut Source(s) of monetary or material Support: Grunenthal,Reade

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### Intervention

Keyword: Cardiovascular, Gout, Risk management

#### **Outcome measures**

#### **Primary outcome**

To assess the prevalence of cardiovascular disease

To assess the prevalence of risk factors for cardiovascular disease

To quantify the risk for cardiovascular disease in patients with gout.

#### Secondary outcome

To investigate the impact of cardiovascular risk management on the risk for

cardiovascular disease in patients with gout in patients who need CV-RM

according to the Dutch guidelines one year after the baseline visit.

To collect more information about the vascular status of patients with

tophaceus gout and contribution of inflammasome activation and oxidative stress

on the atherosclerotic process.

# **Study description**

#### **Background summary**

Gout is the most prevalent disease within rheumatology. Like other rheumatic diseases as rheumatoid arthritis and the spondyloarthropathies, there are indications that the risk for cardiovascular disease is increased in patients with gout. In daily clinical practice, a strong association between hyperuricemia, gout and traditional risk factors for cardiovascular disease as hypertension, dyslipidemia, obesity and diabetes mellitus is observed. The magnitude of this increased risk and whether this is caused by the increased prevalence of traditional risk factors for cardiovascular disease, is not yet clear. Knowledge about the increased risk for cardiovascular disease in patients with rheumatoid arthritis (RA) and other inflammatory joint diseases has led to the implementation of cardiovascular risk management in daily clinical practice.

The goal of cardiovascular risk management is to increase the awareness of this risk and to lower the incidence of cardiovascular morbidity and mortality in these patients. This can be done by preventive measures regarding lifestyle factors as stimulating physical exercise and promoting healthy diets, if necessary in combination with antihypertensive medication or lipid lowering drugs. Although there is evidence that patients with gout have an increased risk for cardiovascular disease, in guidelines recommendations with respect to cardiovascular risk management in patients with gout are lacking. To date, no studies regarding the effect of cardiovascular risk management in gout patients have been conducted, but is likely that in this patient population cardiovascular risk management will lead to a reduction of cardiovascular morbidity and mortality. In summary, there are indications that the risk for cardiovascular disease is increased in patients with gout. However, data about the contribution of individual risk factors is lacking. Available data with respect to the effect of gout treatment on cardiovascular disease are inconclusive. To gain insight in these risk factors, the magnitude of the increased cardiovascular risk and to improve management of cardiovascular risk in patients with gout, data of a larger group of patients should be systematically recorded and evaluated.

#### Study objective

The main objective of this study is to assess the prevalence cardiovascular disease and the prevalence of risk factors for cardiovascular disease in patients with gout, and to quantify the risk for cardiovascular disease in patients with gout. The secondary objective is to investigate the impact of cardiovascular risk management on the risk for cardiovascular disease in patients with gout in patients who need CV-RM according to the Dutch guidelines. The third objective is to get a closer view on the immune system activation (in particular inflammasome) in gout and the possible relationship with the atherosclerotic process. The data that will be collected in this study will serve as the base for a registry of the patients of Reade diagnosed with gout.

### Study design

To be able to address the main objective of this study, a cross sectional study is designed. At this single (baseline) visit demographic, disease specific, cardiovascular and laboratory data will be collected. To evaluate efficacy of cardiovascular risk management, one year later, data with respect to the cardiovascular morbidity and mortality and cardiovascular risk actors will be collected.

From all patients, 20 patients with tophaceous gout will be asked to participate in a subgroup analysis and will go through an extra set of additional examination consisting of ultrasonography, pulse wave velocity measurement and DECT-scan.

#### Study burden and risks

The results of this study will contribute to the knowledge about the increased risk of cardiovascular disease in gout patients and the influence of cardiovascular risk management in this group of patients. Individual subjects will gain no direct benefit from this study. The risk of participating in this study is estimated to be low. The patients will visit our outpatient clinic on 2 occasions for medical history, cardiovascular risk assessment and blood withdrawal.

The extra blood that will be collected for this study will be collected during regular blood sampling. This includes 12.5 ml that will be stored at Reade for the purpose to answer future research questions about cardiovascular disease in gout patients. In addition, during the first visit 22 ml of additional blood will be taken for the purpose of future research into genetic factors that may play a role in gout and cardiovascular disorders.

Furthermore, urine is stored with the aim to carry out further urine testing when necessary for future research questions.

Patients in the subgroup analysis are exposed to radiation once, while undergoing the DECT-scan.

# 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**

Patients:

- Aged 18 years or older
- Diagnosis of gout (first or recurrent episode) confirmed by a rheumatologist

# **Exclusion criteria**

No informed consent Insufficient language proficiency

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-04-2015
Enrollment:	300
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	15-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

# **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 CCMO ID NL46304.048.14