

# Diagnostic value of DECT scan compared to diagnostic needle aspiration

## DEteCTing gout, with or without a needle

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Assessment of value of DECT scan in diagnosing acute arthritis, caused by gout

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42591

### Source

ToetsingOnline

### Brief title

DEteCTing gout

### Condition

- Joint disorders

### Synonym

gout

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Meander Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** DECT gout

## Outcome measures

### Primary outcome

The sensitivity and specificity (95% CI) of DECT scanning for the detection of MSU deposition will be calculated. The area under receiver operating characteristic curve (AUC-ROC) will be employed to evaluate the screening method\*s performance.

### Secondary outcome

Identify the clinical features and laboratory variables that affect the primary outcome measure of positive DECT scan for lesions suggestive of uric acid deposition in patients with acute mono or oligo arthritis.

Establish the additive value of ultrasound guided joint aspiration in patients in whom the first aspirate demonstrated no microscopic MSU and /or no synovial fluid

Establish the additive value of ultrasound guided joint aspiration of DECT lesions suggestive of gout in patients in whom the earlier aspirate(s) demonstrated no microscopic MSU and /or no synovial fluid.

Cost effectiveness analysis of different diagnostic strategies.

Patient satisfaction: What does the patient experience as the most patient-friendly way of diagnosing gout: DECT scan, ultrasound-guided joint aspiration or blind aspiration?

## Study description

### Background summary

Gout is a disease with growing incidence and complexity due to increased life expectancy, co-morbidity and medication. The disease can be diagnosed by microscopy, demonstrating monosodium uric acid (MSU) in synovial fluid of the affected joint or in tophi (subcutaneous or peritendinous MSU depositions). In daily practice, however, the diagnosis is difficult to ascertain due to sampling error (no synovial fluid acquired because the needle was not exactly placed in the affected joint, or the location of the gout might have been extra-articular e.g. around tendons) or to a different cause of acute arthritis (e.g. infection, reactive arthritis). Recently, Dual Energy CT scan has become available. This technique allows the visualization and quantification of MSU. Although imaging modalities such as DECT show promise in the classification of gout, the studies to date have been small and have primarily involved people with established disease.

A study with cross-sectional design in which patients for whom the clinical questions *\*does this patient have gout?\** are referred for participation may contribute to assess the value of DECT scan in diagnosing acute arthritis caused by gout.

### Study objective

Assessment of value of DECT scan in diagnosing acute arthritis, caused by gout

### Study design

Prospective

### Study burden and risks

Benefit: mogelijk eerder stellen van de diagnose

Risk: minimal radiation exposure 0.5 mSV (exposure healthy person 3,6 mSv/year)

## Contacts

### Public

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Age > 18 years

Mono or oligo arthritis (2-3 swollen joints)

Indication for diagnostic aspiration of an inflamed joint in which gout is one of the possibilities

### Exclusion criteria

Polyarthritis ( $\geq 4$  swollen joint);

Crystal proven gout in history

Patient is on uric acid lowering therapy (Allopurinol, Benzbromaron, Febuxostat)

Hip arthritis

Metal or prosthesis of the inflamed joint

Highly suspicion of infectious arthritis

Pregnancy

Contra indication of joint aspiration (skin infection, hemophilia)

No informed consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 25-04-2016

Enrollment: 100

Type: Actual

## Ethics review

Approved WMO

Date: 29-12-2015

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 06-11-2018

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24638  
Source: NTR  
Title:

**In other registers**

Register	ID
CCMO	NL54454.100.15
OMON	NL-OMON24638