Diagnostic value of DECT scan compared to diagnostic needle aspiration DEteCTing gout, with or without a needle

Published: 29-12-2015
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Assessment of value of DECT scan in diagnosing acute arthritis, caused by gout

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	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
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ

NL
Scientific
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ
NL

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 (>=4 swollen joint);
Chrystal 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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54454.100.15
OMON	NL-OMON24638