DEteCTing gout, with or without a needle

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24638

Source
NTR

Brief title
DEteCTing gout, with or without a needle

Health condition

Gout

Sponsors and support

Primary sponsor: Performer: Meander Medical Center
Source(s) of monetary or material Support: self-financing research Meander Medical Center

Intervention

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

a) 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.

b) 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

c) 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.

d) Cost effectiveness analysis of different diagnostic strategies.

e) 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

Rationale: 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.

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

Study design: Prospective

Study population: Patients with acute mono or oligo arthritis without prior diagnosis, the rheumatologist has an indication for diagnostic needle aspiration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In current daily practice, patients with acute mono- or oligo-arthritis without prior diagnosis undergo a diagnostic aspiration of the affected joint. This can be done by blind aspiration or ultra sound guided aspiration depending on the judgement of the rheumatologist. The aspirated synovial fluid is then assessed by polarized microscopy to detect MSU crystals. The diagnostic value of DECT in acute gout attacks had not yet been established and is therefore not used in daily practice. In this study all patients undergo DECT scan to assess the value of DECT scan in diagnosing acute arthritis caused by gout. If the DECT scan demonstrates MSU depositions and the diagnosis of gout was not ascertained prior to DECT scanning by MSU crystals in the synovial fluid, then additional ultrasound guided aspiration will take place, with knowledge of DECT results, followed by repeat microscopy

Study objective

The diagnostic value of DECT in acute gout attacks had not yet been established and is therefore not used in daily practice. In this study all patients undergo DECT scan to assess the value of DECT scan in diagnosing acute arthritis caused by gout.

Study design

week 0,2

Intervention

In this study all patients undergo joint aspiration and DECT scan to assess the value of DECT scan in diagnosing acute arthritis caused by gout. If the DECT scan demonstrates MSU depositions and the diagnosis of gout was not ascertained prior to DECT scanning by MSU crystals in the synovial fluid, then additional ultrasound guided aspiration will take place, with knowledge of DECT results, followed by repeat microscopy.

Contacts

Public
Meander Medisch Centrum, afd Reumatologie; Postbus 1502
R. Klaasen
Amersfoort 3800 BM
The Netherlands
033-8505050
Scientific
Meander Medisch Centrum, afd Reumatologie; Postbus 1502
R. Klaasen
Amersfoort 3800 BM
The Netherlands

033-8505050

Eligibility criteria

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 (¡Ý4 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: Interventional

Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42591
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5682
NTR-old	NTR5826
CCMO	NL54454.100.15
OMON	NL-OMON42591

Study results