# 68Ga-DOTA-NOC PET/CT for the imaging of disease activity in neurologic and cardiac sarcoidosis.

Published: 20-10-2016
Last updated: 14-04-2024

The primary objective of this study is to evaluate the role of 68Ga-DOTA-NOC PET/CT in the imaging of disease activity in suspected neurological and cardiac sarcoidosis and to assess the sensitivity and specificity of 68Ga-DOTA-NOC PET/CT. We...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON42936

**Source**
ToetsingOnline

**Brief title**
SCAN-GO Trial

### Condition

- Respiratory disorders NEC

**Synonym**
pulmonary inflammation, Sarcoidose

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis
**Source(s) of monetary or material Support:** St. Antonius Ziekenhuis

## Intervention

**Keyword:** Disease Activity, PET/CT, Sarcoidosis, Somatostatin

## Outcome measures

**Primary outcome**

Primary parameters:

* 68Ga-DOTA-NOC uptake (SUVmax and SUVmean) in target tissue (myocard and CNS) of sarcoidosis patients.

* Sensitivity and specificity of 68Ga-DOTA-NOC PET/CT to determine sarcoidosis activity in neurological and cardiac sarcoidosis analysis.

Sensitivity and specificity of 68Ga-DOTA-NOC PET/CT will be determined as compared with the diagnostic criteria for *definite* or *probable neurosarcoidosis and a *histological* or *clinical* diagnosis of cardiac sarcoidosis.

**Secondary outcome**

Secondary parameter:

* Correlation between clinical response to immunosuppressive therapy and quantitative uptake measures (myocardial SUVmax and SUVmean for 68Ga-DOTA-NOC).

# Study description

## Background summary

Sarcoidosis is a systemic granulomatous disease most frequently affecting the lungs, although (severe) neurological and cardiac complications are also reported. Currently, there is no gold standard for the assessment of sarcoidosis and disease activity is determined by a combination of clinical investigation, laboratory analysis, chest radiography, 18F-FDG PET/CT and lung function tests. The detection of active neurological and cardiac lesions is especially challenging and there is an unmet clinical need to distinguish active inflammation from inactive disease. In-vivo imaging of (sarcoid) granulomas can be performed using radiolabelled somatostatin analogues and sites revealed in this way are considered to represent active disease. In the past years maging quality was hampered by to the absence of PET tracers, but recently Ga-68 labelled somatostatin analogues have come available.

We hypothesize that 68Ga-DOTA-NOC SSTR-PET/CT is a sensitive and highly specific technique that could provide in a tool that distinguishes active inflammation from inactive disease, and can aid in the clinical decision making process. In this way immunosuppressive therapy can be initiated in those patients who are expected to benefit clinically, with the potential of monitoring treatment effects. Furthermore, patients without active inflammation could be withheld immunosuppressive therapy, thereby eliminating the risk of side effects in a group where no clinical benefit is to be expected.

## Study objective

The primary objective of this study is to evaluate the role of 68Ga-DOTA-NOC PET/CT in the imaging of disease activity in suspected neurological and cardiac sarcoidosis and to assess the sensitivity and specificity of 68Ga-DOTA-NOC PET/CT.

We hypothesize that 68Ga-DOTA-NOC SSTR-PET/CT is a sensitive as well as highly specific method to measure cardiac and neurological sarcoidosis disease activity. This hypothesis is based on known SSTR expression in sarcoid granuloma, and the results of SRS in sarcoidosis. 68Ga-DOTA-SSTR-PET/CT is the gold standard for diagnosis of NET and could prove superior to SRS in sarcoidosis as well.

As secondary objective we plan to correlate the clinical response to immunosuppressive therapy with quantitative uptake measures (myocardial SUVmax and SUVmean for 68Ga-DOTA-NOC). Since SSTR-PET/CT reflects the inflammatory activity within the sarcoid granuloma, we hypothesize that 68Ga-DOTA-NOC uptake predicts the response to immunosuppressive therapy.

## Study design

The study is a prospective single-center pilot (proof of principle) study of consecutive patients with suspected cardiac or neurological sarcoidosis at the Centre of Interstitial Lung diseases, Department of Pulmonology of the St Antonius Hospital.

The study group will be divided into two groups with either suspected cardiac (n = 30) or neurological (n = 10) sarcoidosis.

**Study burden and risks**

In addition to the St Antonius Hospital sarcoidosis work-up, the additional medical research will entail a 68Ga-DOTA-NOC PET/CT. The administered dose will be approximately 150 MBq 68Ga-DOTA-NOC. With a dose equivalent of 1.7 x 10-2 mSv/MBq this will entail an additional effective radiation dose of 2.55 mSv [25]. The effective radiation dose of the CT acquisition of the chest for attenuation correction and localisation will be 1 mSv resulting in a cumulative effective dose of 3.55 mSv for the PET/CT procedure per subject. This is comparable to 1.4 times the yearly radiation dose for the Dutch population.

The amount of DOTA-NOC, an octreotide analogue, used for 68Ga-DOTA-NOC PET/CT involves a maximum of 40 microgram. This is in conformance with the limit of 50 microgram in the Ph. Eur. monograph as well as the EANM guideline on PET/CT tumour imaging with 68Ga-DOTA-conjugated peptides, as this amount is expected to have no clinically significant pharmacological effect. 68Ga-DOTA-NOC is a radiopharmaceutical used worldwide since 2003 and is included in the previously mentioned 2010 EANM guideline.

68Ga-DOTA-NOC PET/CT has been in routine use for the diagnosis of NET in the St Antonius Hospital since September 2014, in accordance with the local pharmacovigilance procedure for radiopharmaceuticals without a marketing authorization.

# 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

* Men and women > 18 years
* Suspected cardiac sarcoidosis: patients with histologically proven extracardiac sarcoidosis, presenting with either an abnormal ECG, abnormal echocardiogram or symptoms of palpitations/pre-syncope or syncope
* Suspected neurosarcoidosis; patients presenting with symptoms suggestive of central nervous system involvement or with abnormalities during neurologic examination

## Exclusion criteria

* Pregnancy or nursing
* Mental health problems interfering with participation
* Treatment with systemic corticosteroids or other immunosuppressive drugs in the year prior to screening
* History of ischemic heart disease
* Any type of myocardial disease
* Uncontrolled diabetes mellitus

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-01-2017 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | n.a. |
| Generic name: | Gallium-68-DOTA-NOC |

# Ethics review

Approved WMO

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| Date: | 20-10-2016 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

Approved WMO

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|---|---|
| Date: | 22-11-2016 |
| Application type: | First submission |
| 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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2016-002160-14-NL |
| CCMO | NL58209.100.16 |