Comparison of the diagnostic value of Ga-67 scan and F-18 DG PET in sarcoidosis patients

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Comparison of the diagnostic value of Ga-67 and F-18 DG-PET in sarcoidosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON34129

Source
ToetsingOnline

Brief title
Gallipet Study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Noncaseating granulomatous disease

Research involving
Human

Sponsors and support

Primary sponsor: nucleaire geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W,VUMC

Intervention

Keyword: F-18 DG PET, Ga-67 scan, sarcoidosis, sensitivity

Outcome measures

Primary outcome

The main study parameter is the uptake of Ga-67 citrate and F-18 DG in patients with active sarcoidosis. Ga-67 scan and F-18 DG PET will be evaluated by three independent nuclear physicians, who are blinded for the clinical data. Since all patients are symptomatic and histology is obtained at the time of inclusion, these findings are used a the *gold standard* for active sarcoidosis. Due to the absence of an internationally accepted gold standard for sarcoidosis activity, the specificity can not be determined.

The results will be presented as sensitivity and inter observer agreement.

Secondary outcome

not applicable

Study description

Background summary

Ga-67 scan is currently an accepted diagnostic method in the evaluation of sarcoidosis activity and/or the extend of this disease. Recently, F-18 DG PET has come up as a potential new molecular imaging technique in sarcoidosis. Marked discrepancies in favour of F-18 DG PET images have been observed in some of our patients who underwent both Ga-67 and F-18 DG PET. Some patients with active pulmonary disease showed almost no uptake on the Ga-67 scan but fairly positive lesions on F-18 DG PET. Furthermore, F-18 DG PET demonstrated extra-pulmonary sarcoidosis lesions which were not visible on Ga-67 scan. This led to the hypothesis that F-18 DG-PET imaging might be the superior nuclear imaging technique in the assessment of sarcoidosis activity and extend, which might have consequences with regard to treatment planning.

Study objective

Comparison of the diagnostic value of Ga-67 and F-18 DG-PET in sarcoidosis.

Study design

The study is designed as an observational cohort study.

Study burden and risks

Participation will entail one extra visit at the hospital and a small increase of total body dose due to radiation.
However, the diagnostic value of F-18 DG PET is considered very high and dose reduction in future patients is substantial, so we think this will justify our research.

Contacts

Public
Selecteer

Koekoekslaan 1
3435 CM Nieuwegein
Nederland
Scientific
Selecteer

Koekoekslaan 1
3435 CM Nieuwegein
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Active sarcoidosis

Exclusion criteria

Pregnancy
Younger than 18 years old
Immunosuppressive therapy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2006
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2006
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-03-2009
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

No registrations found.

In other registers

Register	ID
CCMO	NL13270.100.06