# The Promysed Land: Clinical use of additional cardiac imaging and biomarkers in diagnosis and evaluation of cardiac sarcoidosis

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Myocardial disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON48167

**Source**
ToetsingOnline

**Brief title**
The Promysed Land

### Condition

- Myocardial disorders

**Synonym**
Cardiac sarcoidosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Foundation for Sarcoidosis Research

**Source(s) of monetary or material Support:** Foundation for Sarcoidosis Research

## Intervention

**Keyword:** Cardiac sarcoidosis, Sarcoidosis with heart involvement

## Outcome measures

**Primary outcome**

PAPLAND

• The rate of diagnosis/incidence of cardiac sarcoidosis in sarcoidosis patients who are not suspected to have cardiac involvement based on initial evaluation using history and ECG.

PROMyS

• Death or heart transplant;

• Cardiac hospitalization;

• Defibrillator therapy (appropriate and inappropriate);

• Need for RFA;

• Change in ejection fraction;

• Proportion of patients requiring various medical therapies for management;

• Cardiac events (heart block, VT, atrial arrhythmias, cardiac arrest);

• Pacingpercentage.

**Secondary outcome**

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# Study description

## Background summary

Cardiac involvement is the second leading cause of death in patients with sarcoidosis. Knowledge about the natural history of the disease and early diagnosis is important for adequate clinical management.

## Study objective

The aim of the study is in threefold: Firstly, examine whether conventional screening for cardiac involvement based on history and ECG followed by routine use of echocardiogram with strain and Holter monitoring will identify more patients with cardiac sarcoidosis compared to screening based on conventional screening alone. In addition, we aim to examine the sensitivity of detecting cardiac sarcoidosis using conventional screening and determining the rate of diagnosis of cardiac sarcoidosis in sarcoidosis patients who had initial negative conventional and second-tier screening tests after undergoing these screening tests again at 24 months. Secondly, we aim to define the natural history of cardiac sarcoidosis in a broad sarcoidosis population, identify prognostic predictors, assess whether suspected isolated cardiac sarcoidosis behaves differently than conventional cardiac sarcoidosis and assess the implications of abnormal screening tests in individuals without advanced imaging (MRI, PET) abnormalities. Thirdly, we aim to evaluate the effect of anti-sarcoidosis therapy for cardiac sarcoidosis and evaluate the change in serum levels of Troponin T Gen 5, and NT-proBNP with reductions in anti-sarcoidosis therapy for cardiac sarcoidosis.

## Study design

This study will have two arms: a screening (PAPLAND) and registry-arm (PROMyS). PAPLAND is a prospective randomized un-blinded trial for cardiac sarcoidosis comparing the addition of echocardiogram with strain and Holter monitoring to conventional clinical follow-up. The PROMyS-arm consists of a prospective multicenter registry of suspected and confirmed cardiac sarcoidosis patients and biomarker sub study.

## Study burden and risks

PAPLAND-arm: The use of (ambulatory) ECG and echocardiogram pose no risk, since these tests are noninvasive, do not use radiation and are painless. It is, however, possible that patients experience skin irritations from gel or paste used to attach the electrodes. In addition, prolonged contact with these electrodes may also cause skin irritation. Nevertheless, we do not expect serious complications caused by these tests. The use of cardiac MRI also is not harmful for patients based on the fact that no radiation is required for this kind of imaging.

Biomarker sub study: venous blood samples are needed. Venipuncture is a procedure with minimal risks. Patients may however, experience inconveniences during and after blood draw, for example: hematoma, pain in the arm, etc.

## 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

Papland:
• Diagnosis of sarcoidosis as per ATS guidelines

Promys:
• Sarcoidosis as defined by WASOG/ATS/ERS guidelines -or- clinical scenario highly suspicious for isolated cardiac sarcoidosis in patients with no evident extra cardiac disease;

• Suspected cardiac sarcoidosis as defined by suggestive symptoms, ECG, echocardiogram, ambulatory ECG monitoring, or advanced cardiac imaging studies, in the opinion of the principal investigator; Diagnostic suspicion for CS must have occurred less than 12 months prior to the date of enrollment.

Biomarker substudy:
• Sarcoidosis as defined by WASOG/ATS/ERS guidelines
• Presence of cardiac sarcoidosis as defined by established criteria.
• Willing to participate in a study that involves return visits with phlebotomy (9 moments)

### Exclusion criteria

Papland:
• Referred to the enrolling center to evaluate for suspected cardiac sarcoidosis.
• Pre-existing high suspicion for cardiac sarcoidosis, defined as having had cardiac MRI or cardiac PET scan ordered by other institutions.

Promys:
• No plans for routine follow-up at the enrolling center.
• Extra-cardiac disease likely to interfere with follow-up (e.g. life-threatening pulmonary or neurologic sarcoidosis; or life-threatening non-sarcoidosis diseases likely to result in death within 12 months, in the opinion of the investigator.
• Cardiac sarcoidosis diagnosed by the enrolling center more than 12 months prior to inclusion in the registry.
• Treatment administered specifically for cardiac sarcoidosis more than 12 months prior to enrollment, regardless of location, and regardless of whether other organs were also treated, as long as CS was part of the treatment target, in the opinion of the investigator.
• Currently listed for a heart transplant.

Biomarker substudy:
• All of the exclusion criteria listed for the overall registry
• Presence of an active infiltrative cardiomyopathy with the exception of a sarcoidosis cardiomyopathy.
• Patients with active angina, active acute coronary syndromes, or other cardiac diseases associated with elevated serum troponin.
• Presence of crescendo angina or active myocardial infarction

## Study design

### Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-06-2021 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 18-03-2020 |
| 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 |
| --- | --- |
| CCMO | NL71111.100.19 |