

# Genetic background of Löfgren's Syndrome

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The aim of this study is to investigate if there are genetic factors predisposing to Löfgren's syndrome, and whether these factors have an influence on the clinical course.

|                              |                        |
|------------------------------|------------------------|
| <b>Ethical review</b>        | Approved WMO           |
| <b>Status</b>                | Recruitment stopped    |
| <b>Health condition type</b> | Immune disorders NEC   |
| <b>Study type</b>            | Observational invasive |

## Summary

### ID

NL-OMON33149

### Source

ToetsingOnline

### Brief title

LOFGREN

### Condition

- Immune disorders NEC
- Respiratory disorders NEC

### Synonym

Acute sarcoidosis, Besnier-Boeck-Schaumann

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** acute sarcoidosis, löfgren's syndrome, sarcoid arthritis, sarcoidosis

## Outcome measures

### Primary outcome

To investigate an association between the genetics and the susceptibility to Löfgren's syndrome, DNA analysis will be done. For the genomic DNA extraction whole blood will be used. When a genetic predisposition is found, in vitro proliferation and cytokine production assays will be performed to investigate the functional effects.

### Secondary outcome

Our secondary objective is to investigate the blood analysis, pulmonary function tests and radioscopic examination to distinguish between the patients having a good and a bad prognosis. And to find parameters that could have predicting value about the course and outcome of the disease.

## Study description

### Background summary

Löfgren's syndrome is an acute and usually self-remitting phenotype of sarcoidosis. Recent works indicate specific genetic background, infectious transmission and exposure to environmental agents as main causes of sarcoidosis. One could hypothesize that genetically predisposed hosts who are exposed to certain environmental triggers are likely to develop the disease.

### Study objective

The aim of this study is to investigate if there are genetic factors predisposing to Löfgren's syndrome, and whether these factors have an influence on the clinical course.

## Study design

An observational study

## Study burden and risks

The patients will only come for one visit, and during this visit the anamnesis will be taken, physical examination, pulmonary function test, radioscopic examination and drawing blood will be done.

The risks of drawing blood from a vein are minimal.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Patients diagnosed with Löfgren's syndrome.
- Löfgren's syndrome is defined according to the latest ATS/ERS/WASOG statement as presenting the clinical features, i.e.:
  - o Acute symptoms like fever
  - o Bilateral hilar lymphadenopathy on chest radiograph
  - o Erythema nodosum and/or joint symptoms (marked periarticular inflammation or arthritis of the ankles)
- Capability of giving informed consent

## Exclusion criteria

patients with:

- Non-Löfgren sarcoidosis
- Other granulomatous diseases

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-06-2009

Enrollment: 300

Type: Actual

## Ethics review

Approved WMO

|                    |   |
|--------------------|---|
| Date:              | 16-04-2009  |
| 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     | NL26386.100.08 |