# T cell respons in legionella

Published: 04-04-2019
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To evaluate the diagnostic potential of the elispot Legionella for identifying patients with Legionella disease

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON48272

**Source**
ToetsingOnline

**Brief title**
TRILO-study

### Condition

- Bacterial infectious disorders

**Synonym**
Legionella disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Diakonessenhuis Utrecht
**Source(s) of monetary or material Support:** Maatschap Medische Microbiologie en Immunologie;Maatschap longziekten

### Intervention

**Keyword:** Diagnostic, Elispot, Legionella, T-cell

## Outcome measures

### Primary outcome

Diagnostic potential of the elispot to identify Legionella disease patients

### Secondary outcome

To evaluate the T-cell respons in time in patients with a Legionella infection

# Study description

### Background summary

Legionellosis is difficult to diagnose

### Study objective

To evaluate the diagnostic potential of the elispot Legionella for identifying patients with Legionella disease

### Study design

Observational study to evluate a new diagnostic tool

### Study burden and risks

None besides the risk of a venapunction

# 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

(group1) Hospitalized Patients with a proven Legionella infection (positive Legionella urine antigen test/ culture/ PCR) of which a subgroup willing to participate to the follow up study
(group 2) healthy volunteers matched for age and gender
(group 3) Patients with clinical presentations of pneumonia and a proven other pathogen

## Exclusion criteria

• immunosuppressive medication
• < 18 years
• Incapacitated patients not able to give informed consent

# Study design

## Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

| | |
|---|---|
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-08-2019 |
| Enrollment: | 270 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 04-04-2019 |
| 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 | NL68503.100.18 |