# Pathogenic role of virus-specific T-cells in corneas of patients with herpetic stromal keratitis (HSKPATH)

Published: 21-01-2020 Last updated: 10-04-2024

Elucidation of the pathogenic role of cornea-infiltrating HSV-specific T-cells in HSK patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Ocular infections, irritations and inflammations
Study type	Observational non invasive

# Summary

### ID

NL-OMON47972

**Source** ToetsingOnline

**Brief title** HSKPATH

### Condition

- Ocular infections, irritations and inflammations
- Viral infectious disorders

**Synonym** herpetic keratitis

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** NIH

### Intervention

Keyword: HSV, keratitis, surplus tissue

### **Outcome measures**

#### **Primary outcome**

Characteristics of HSV-specific T-cells in diseased cornea tissue specimens of

HSK and non-HSK patients.

#### Secondary outcome

None

# **Study description**

#### **Background summary**

Herpes simplex virus type 1 (HSV-1) infection of the cornea may lead to herpetic stromal keratitis (HSK), a major cause of corneal blindness worldwide. Cornea-infiltrating HSV-specific T-cells are considered pivotal in the pathology of HSK, but their phenotype, viral antigen specificity and effector mechanisms remain largely unknown. Detailed characterization of virus-specific T-cells in surplus post-transplant corneal specimens from patients with HSK, and non-infectious cornea disorders (non-HSK) included as disease controls, may provide clues to develop new intervention strategies aimed to inhibit their pathogenic effector function.

#### **Study objective**

Elucidation of the pathogenic role of cornea-infiltrating HSV-specific T-cells in HSK patients.

#### Study design

Prospective, non-randomised and observational

#### Study burden and risks

Participants do not benefit directly, risks are negligible, and burden is low.

# Contacts

**Public** Erasmus MC, Universitair Medisch Centrum Rotterdam

'Gravendijkwal 230 Ee1720a Roterdam 3015GE NL **Scientific** Erasmus MC, Universitair Medisch Centrum Rotterdam

'Gravendijkwal 230 Ee1720a Roterdam 3015GE NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

Age >= 18 years. Immunecompetent individual. Positive HSV-1 infected Documented ocular disease history for at least 1 year. Indication for therapeutic corneal transplantation\*

### **Exclusion criteria**

Individuals with documented HIV, HBV or HCV infection. Individuals on immune therapy or did so in the past 3 months.

# Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	65
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	21-01-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

# **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

ССМО

**ID** NL71647.078.19