

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

Published: 21-01-2020

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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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age $\geq$ 18 years.

Immunocompetent 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
Type:	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	ID
CCMO	NL71647.078.19