Clinical implications of asymptomatic corneal shedding of herpes simplex virus

Published: 15-01-2020
Last updated: 10-04-2024

Objective: To determine the incidence of asymptomatic oral and corneal HSV-1 shedding.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eye disorders
Study type	Observational invasive

Summary

ID

NL-OMON48221

Source
ToetsingOnline

Brief title
CORSURV

Condition

- Eye 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: Stichting voor Ooglijders (Rotterdam)

Intervention

Keyword: herpes simplex virus, herpetic keratitis, shedding

Outcome measures

Primary outcome

Main study parameters/endpoints: Proportion of HSV-1 DNA positive oral and

corneal samples.

Secondary outcome

Not applicable

Study description

Background summary

Rationale: HSV-1 infections are a leading cause of corneal disease. Therapeutic intervention of herpetic keratitis involves systemic or topical treatment with antivirals. Long-term antiviral therapy may, however, increase the risk of therapy-resistant HSV-1 strains and consequently poor visual outcome. It is conjectured that asymptomatic, corneal viral shedding may serve 1) as a substitute outcome parameter for efficacy of treatment, and 2) as a diagnostic tool to determine the antiviral susceptibility profile.

Study objective

Objective: To determine the incidence of asymptomatic oral and corneal HSV-1 shedding.

Study design

Study design: Prospective, observational.

Study burden and risks

With respect to their health care, subjects do not benefit from participation, risks are considered to be mild/moderate. As the burden of participation is substantial, participants will be financially compensated.

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 * 18 years.
- Informed consent.
- Immunecompetent individual.
- Positive HSV-1 infection status
- No symptomatic ocular HSV-1 disease during 3 months preceding first study sampling.
- No anti-HSV therapy during 1 month preceding first study sampling.
- No immunesuppressive drugs during the 3 months preceding first study sampling.
- No previous keratoplasty

Exclusion criteria

- Individual not able to adhere to bi-daily oral and corneal sampling for 30 consecutive days.
- Individuals wearing contact lenses

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2020
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2021
Application type:	Amendment
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	NL70957.078.19