Quantitative monitoring of the inflammatory process in active HSV keratitis by in vivo confocal microscopy, a pilot study.

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Testing the hypothesis that stromal reflectivity, assessed by confocal microscopy, is a reliable quantitative measure for the inflammatory process due to HSV keratitis.

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

Summary

ID

NL-OMON31356

Source
ToetsingOnline

Brief title
Monitoring of HSV keratitis by confocal microscopy.

Condition

- Ocular infections, irritations and inflammations

Synonym
herpetic keratitis

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek

Oogziekenhuis - Prof. Dr. H. J. Flieringa.

Intervention

Keyword: Confocal microscope, Herpes Simplex Virus 1, Keratitis

Outcome measures

Primary outcome

- Confocal microscope:

Stromal reflectivity (Z-scan, Area Under the Curve (AUC)) of HSV eye.

- Clinical scoring form.

Secondary outcome

- Confocal microscope:

Stromal reflectivity (Z-scan, AUC) fellow eye,

Stromal reflectivity after 10 minutes HSV Eye (test reproducibility),

Total corneal reflectivity,

Reflectivity of anterior, median and posterior stroma separately.

- Pachymetry:

Tomey,

Pentacam.

- Slit lamp (maximal resolution):

photograph central cornea,

photograph paracentral cornea,

blue light photograph (fluorescein drop),

overall corneal photography.

- Clinical scoring form based on slit lamp photography.

- Vision:

BCVA (ETDRS chart),

Contrast sensitivity (Pelli-Robson chart),

Intraocular stray light (Oculus C-quant).

Study description

Background summary

Confocal microscopy is a non-invasive, real-time, in vivo imaging technique which has been put forward as a potential clinical tool for inspection of the cornea. Presently, active Herpes Simplex Virus-1 (HSV) keratitis is evaluated by slit lamp inspection. For an objective follow up of the inflammatory process, however, this method does not meet the standards of sufficient accuracy and reproducibiltiy. In this study, it will be investigated whether the improved image quality of the most recent version of the confocal microscope can provide a reliable quantitative parameter for a more adequate follow up of the inflammatory process of active HSV keratitis.

Study objective

Testing the hypothesis that stromal reflectivity, assessed by confocal microscopy, is a reliable quantitative measure for the inflammatory process due to HSV keratitis.

Study design

Prospective cohort study.

Study burden and risks

Study-related measurements will be performed during clinical visits and will take approximately 40 minutes extra time. Participants of this study do not benefit from the results of this study. Risks are negligible.

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.
Unilateral active keratitis.

Exclusion criteria

Corneal irregularity.
Recently deteriorating cataract.
Recently deteriorating retinal lesion.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2007
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	NL17615.078.07