Monitoring the inflammatory process in active herpetic keratitis by in vivo confocal microscopy (IVCM): Clinical relevance.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27960

Source
Nationaal Trial Register

Health condition

Herpetic keratitis

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam (OZR)
Postbus 70030
3000-LM Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis ¨C Prof. Dr. Flieringa (SWOO)

Intervention

Outcome measures

Primary outcome

BCVA at 12 and 24 months follow up. Number of recurrences recognized in an earlier state by

IVCM compared to slit lamp examination.

Secondary outcome

1. Side effects of treatment;

2. Amount of steroids used during 24 months follow up;

3. Dose of antiviral treatment used during 24 months follow up.

Study description

Background summary

Rationale:

Confocal microscopy is a non-invasive, real-time, in vivo imaging technique which has been put forward as an additional clinical tool for inspection of the cornea. Presently disease activity of herpetic 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 reproducibility. A large study on endothelial involvement in herpetic keratitis showed that In Vivo Confocal Microscopy (IVCM) has an additional role in detecting active endotheliitis which remains undetected in slit lamp examination. In a pilot study we investigated the role of confocal microscopy as reliable quantitative parameter for a more adequate follow up of the inflammatory process of active herpetic keratitis.

Objective:

Testing the hypothesis that IVCM is a clinical relevant tool to monitor the inflammatory process due to herpetic keratitis.

Study design:

Prospective randomised study.

Study population:

All patients with herpetic stromal keratitis (HSK) already known to the Rotterdam Eye

Hospital, and all new patients presenting with herpetic keratitis.

Main study parameters:

BCVA at 12 and 24 months follow up. Number of recurrences recognized in an earlier state by IVCM compared to slit lamp examination.

Secondary study parameters:

Side effects of treatment. Amount of steroids used during 24 months follow up. Dose of antiviral treatment used during 24 months follow up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The normal frequency of consultations in HSK following a recurrence is 7 times during the first year (i.e. day 0, week 1, months 1, 3, 6, 9, 12), and two times during the second year. Patients with inactive disease are normally followed every 6 months.

Study-related measurements will be performed during all normally planned clinical visits, with a minimum frequency of 4 times a year. Thus, 2 extra visits are anticipated for the 'recurrent HSK' group (i.e. during the second year of follow-up); 'inactive HSK' patients will have to pay 4 extra visits during the entire 2-year follow-up period.

The study-related measurements will take about 40 minutes during the first visit and 20 minutes during the subsequent visits (total extra time for the 'recurrent' group: 40 + 10 x 20 = 240 minutes; total extra time for the 'inactive' group 40 + 7 x 20 = 180 minutes).

Participants of this study do not benefit from the results of this study. Risks are considered to be negligible.

Study objective

IVCM is a clinical relevant tool to monitor the inflammatory process due to herpetic keratitis.

Study design

D0, W1, M1, M3, M6, M9, M12, M15, M18, M21, M24.

Intervention

The diagnostic method used in this study to adjust medication will depend on the study-arm. Diagnostic outcome (active versus inactive HSK) will determine whether treatment is (re)started or stepped up.

Contacts

Public
PO Box 70030
L. Remeijer
Rotterdam 3000 LM
The Netherlands
Scientific
PO Box 70030
L. Remeijer
Rotterdam 3000 LM
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age ¡Ý 18 years;

2. Informed consent;

3. Unilateral disease;

4. Immune stromal keratitis in herpetic infection involving the optical axis;

5. Capable to cooperate (sitting still, fixing test light);

6. Group 1 and 2: At least 6 months after a clinical overt recurrence;

7. Group 3 and 4: At presentation with recurrence.

Exclusion criteria

1. Patients with proven ACV resistant strains;

2. Severe necrotizing herpetic keratitis;

3. Severe herpes related macula in the optical axis preventing visualisation of endothelium;

4. Herpetic stromal infection exclusively located in the peripheral 2 mm of the cornea;

5. Pre-existing ocular disease requiring surgical intervention within 12 months;

6. Pre-existing uncontrolled steroid glaucoma.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	06-12-2010
Application type:	First submission

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
NTR-new	NL2522
NTR-old	NTR2640
Other	OZR / METC : 2009-35 / 2010-279 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A