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

Gepubliceerd: 06-12-2010 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27960

Bron
Nationaal Trial Register

Aandoening

Herpetic keratitis

Ondersteuning

Primaire sponsor: Het Oogziekenhuis Rotterdam (OZR)
Postbus 70030
3000-LM Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek Oogziekenhuis ¨C Prof. Dr. Flieringa (SWOO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-12-2010

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A