Determination of protein profiles in vitreous of eyes with endophthalmitis with Surface Enhanced Laser desorption/ ionization time-of-flight (SELDI-tof) technology.

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To evaluate the usefulness of SELDI-tof (surface enhanced laser desorption/ ionisation-technology) technology in determination of disease-specific protein profiles of bacteria in vitreous of patients with endophthalmitis after cataract surgery....

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

Summary

ID

NL-OMON33140

Source
ToetsingOnline

Brief title
Detection of infection with SELDI-tof in case of endophthalmitis

Condition

- Ocular infections, irritations and inflammations

Synonym
Infection of vitreous, inflammation of ocular fluid

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: de F.P Fischer Stichting

Intervention

Keyword: endophthalmitis, infection, SELDI-tof, vitreous

Outcome measures

Primary outcome

Three analyses will be performed with SELDI-tof in comparison to regular

culture methods:

1. Comparison of protein composition of vitreous in comparison to

serum obtained bij surgery for maucular hole or

macular pucker: controll population

2. Comparison of protein composition of vitreous in comparison to

serum of patients with endophthalmtis

3. Comparison of protein composition of vitreous in comparison to

serum of patients with endophthalmitis versus

the controll population.

Secondary outcome

1. Evaluation of the correlation between specific bacterial causes

of endophthalmitis indentified by culture and

specific protein pattern obtained via SELDI-tof analyses.

2. Evaluation of the correlation of vitreous of endophthalmitis

with a negative result with culture and the protein

pattern obtained by SELDI-tof analyses. We will compare the

protein patterns of culture negative results with

peak pattern of bacteriae identified by culture.

Study description

Background summary

Endophthalmitis is a form of ocular inflammation which is clinically diagnosed. The inflammation is primarily located in the vitreous and fluid of the anterior chamber. The patient experiences serious visual loss, frequently combined with intense ocular redness and pain. The inflammation is diagnosed with biomicroscopy. Infection is confirmed by culturing of the vitreous. Endophthalmitis is treated with wide-spectral antibiotics which are injected in the vitreous.

Based on the outcome of the bacterial culture, treatment can be adapted to match the diagnosed bacterium. In case of endophthalmitis, that develops within 6 weeks after cataract surgery, the bacterial species is identified in 70% of vitreous samples. However, in 30% no bacterial growth is determined. (1) Until today, it is not known whether negative cultures represent sterile inflammations or infections in which the bacterial load is to low to yield a positive culture. An additional disadvantage of regular culture methods is the fact that they require at least 1-3 days. With new techniques the diagnostic process of endophthalmitis could be optimised.

SELDI-tof analyses protein content in body fluids. This technique is extremely suitable for microvolumia, since only 1 microlitre is required for analysis. The proteins bind to microchips, are ionised by laser and subsequently catapulted into a vacuum tube. The speed of migration of the proteins through the tube (time of flight) defines the mass of the protein. The different masses of diverse proteins result in a pattern of peaks. Inflammation-specific biomarkers or bacterial-specific biomarkers can be identified by comparing profiles of different patient groups (endophthalmitis versus controls). SELDI-tof technology has proven to be very effective in detecting the cause of intra-amnion infections, SARS and congenital CMV hepatitis. (2,3,4) The protein profiles proved highly sensitive en specific for a diversity of bacteria and viruses.

Currently no information is available about the utility of SELDI-tof technology of research in ocular fluids. In this study, SELDI-tof technology is used as a new diagnostic test in ocular inflammation based on infection. The high degree of sensitivity and specificity of SELDI-tof technology (2,3,4) in combination with a diagnostic process of only several hours could be a valuable addition to

current diagnostic methods.

Referencies:

1. Results of the Endophthalmitis Vitrectomy Study. A randomized trial of immediate vitrectomy and of intravenous antibiotics for the treatment of postoperative bacterial endophthalmitis. Endophthalmitis Vitrectomy Study Group. Arch Ophthalmol 1995;113:1479-96.
2. Gravett MG, Novy MJ, Rosenfeld RG, et al. Diagnosis of intra-amniotic infection
by proteomic profiling and identification of novel
biomarkers.
JAMA 2004;292:462-9.
3. Kang X, Xu Y, Wu X, et al. Proteomic fingerprints for potential application to early
diagnosis of severe acute respiratory syndrome. Clin Chem
2005;51:56-64.
4. Ward DG, Suggett N, Cheng Y, et al. Identification of serum biomarkers for colon
cancer by proteomic analysis. Br J Cancer 2006;%19;94:1898-905.

Study objective

To evaluate the usefulness of SELDI-tof (surface enhanced laser desorption/ ionisation-technology) technology in determination of disease-specific protein profiles of bacteria in vitreous of patients with endophthalmitis after cataract surgery.
Protein profiles of vitreous samples from endophthalmitis patients with a negative culture will be compared to those from patients in which the bacterial cause is identified.

Study design

The patients with endophthalmitis will all have developed endophthalmitis within 6 weeks after cataract surgery. Treatment of this disease exists of retro bulbar anaesthesia followed by a vitreous biopsy (0.2-0.3 ml) with a vitrectome. After biopsy broad spectral antibiotics are injected in the vitreous cavity. The vitreous biopsy is sent for microbiological culture. For the current research 0.1 ml vitreous will be kept and frozen at -80 degrees Celsius. Additionally, of 10 patients a blood sample will be drawn. After centrifuging the blood, serum will be aspirated and frozen at -80 degrees Celsius. Both serum and vitreous will be coded before storage on the department of Virology to protect the privacy of the patient.

Study burden and risks

The collection of blood samples will only take place after permission of the patient through signing informed consent. The risk of taking the bloodsample will be equal to the general risk of taking the bloodsamples as is done in eg. out patients clinic.

Patients will not experience any additional discomfort f withdrawel of the vitreous sample, because of all 3 patient groups a minimum of 0.2 ml vitreous for culture or more (in case of pars plana vitrectomy) is extracted for therapeutic purposes. The minimum required amount of vitreous for culture is 0.1 ml. Consequently, no extra vitreous needs to be collected for this study. Both samples of vitreous and serum will be coded before arrival on the department of Virology to protect patients privacy.

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

Patients with endophthalmitis:
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-Age >= 18 years
-initiation of endophthalmitis within 6 weeks after cataract surgery;Controll group:
-wils
- Age >= 18 years
-patient that undergo a pars plana vitrectomy because of a macular hole or macular pucker.

Exclusion criteria

Endophthalmitis group:
-patients able to give informed consent
-previous uveitis in the affected eye
-previous pars plana vitrectomy in the affected eye.;Controll group: macylar hle/ macular pucker
-retinopathy because of Diabetes Mellitus or previous uveitis in the affected eye
-previous pars plana vitrectomy in the affected eye.;-

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2009
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	07-07-2009
Application type:	First submission
Review commission:	METC NedMec

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	NL26551.041.09