Glaucoma and other ocular complications in herpetic and HLA-B27 associated anterior uveitis.

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With this research we want to determine the prevalence of glaucoma and temporary IOP elevations in our own anterior uveitis population, with a clear definition of glaucoma and IOP elevation. We will study two groups of patients, all with anterior...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON37375

Source
ToetsingOnline

Brief title
Glaucoma and other ocular complications in anterior uveitis.

Condition

- Glaucoma and ocular hypertension

Synonym
anterior uveitis, eye inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Wordt aangevraagd: Prof. Mulder stichting;Stichting Nederlands Oogheelkundig Onderzoek

Intervention

Keyword: anterior uveitis, glaucoma, herpes, HLA-B27

Outcome measures

Primary outcome

Primary outcome measures:

• Intraocular pressure at presentation of first uveitis episode. (retrospective)

• Intraocular pressure at the following uveitis episodes at first visit. (retrospective)

• Course of intraocular pressure during treatment and control moment of uveitis.(retrospective)

• Time of onset of glaucoma (after how many episodes / active duration). (retrospective)

• Use of anti-glaucomatous agents. (Only treated during IOP elevation or also between IOP elevations. The total number of glaucoma medication used, is noted.) (retrospective)

• Applied glaucoma surgery. (retrospective)

• Use steroid eye drops. (retrospective / present status)

• Current IOP, visual fields and optic disc status. (present status)

• Duration of follow-up. (retrospective)

Secondary outcome

Secondary outcomes:

• Secondary cataract (corticosteroid-induced). (retrospective / present status)

• Formation of anterior synechiae and / or posterior synechiae. (present status)

• Formation of cystoid macular edema. (retrospective / present status)

• Visus (present status)

• Slit lamp examination: presence of iris transillumination (radial, sector),

pseudoexfoliation, Krukenberg's spindle. (present status)

• Central corneal thickness (pachymetry) (retrospective / present status)

• Glaucoma risk factors (family history, myopia, race) (present status)

Study description

Background summary

Secondary glaucoma is one of the major ocular complications of uveitis. The prevalence, clinical symptoms and the mechanism of elevated intraocular pressure vary depending on the cause of the uveitis. The obstruction of the drainage of aqueous humor may be reversible (for example, by the accumulation of inflammatory cells into the intertrabecular space, edema of the trabecular lamellae, or a closed chamber angle by swelling of the ciliary body) or is irreversible (by, for example scarring). Because glaucoma can lead to a significant decrease in visual function, it is important to not only evaluate the inflammatory reaction in patients with uveitis, but also the intraocular pressure and visual fields.

The standard therapy in anterior uveitis is giving steroid eye drops. In the beginning, often with a high frequency, depending on the inflammatory activity. After a week, the inflammatory activity in the anterior chamber has to be reduced to about half of the number of cells that was seen in the first presentation. It is important that patients frequently come to the outpatient clinic to monitor the reduction of the inflammatory activity, and if necessary, to adjust the treatment. The frequency of the outpatients controls depends on the severity of the inflammatory activity. If there is no reduction of the inflammatory activity, a periocular injection of steroids or a course of oral prednisolone is to consider. It is also advisable to prescribe pupil dilating eyedrops, such as atropine, until the inflammation has decreased. This to prevent the formation of posterior synechiae to the iris and to give the iris more time to recover. There is no standard research on glaucoma. Only when patients have a high IOP, for a longer period of time, a visual field test (perimetry) will be performed. Patients with only a few temporary IOP elevations are usually not examined.

So far there is no consensus on the prevalence of glaucoma in patients with anterior uveitis based on HLA-B27 positivity. The values **range from 0-19%. The measured prevalence of temporary IOP increase during active inflammation varies from 5-21%. The definition of glaucoma, in all these studies differs, or is missing, so that comparing these numbers is difficult. In these studies it is indicated that temporary IOP elevations occur during the inflammatory phase, but it is not mentioned whether this is at presentation or later in the course of the uveitis, making it difficult to determine whether the IOP rise occurs as a result of active uveitis, the use of corticosteroids or secondary changes in the chamber angle (anterior synechiae). It is well known that ocular hypertension is one of the side effects of corticosteroid eye drops. This usually occurs after extended use (weeks to months). Furthermore, in the studies done so far only the prevalence of glaucoma and sometimees the prevalence of a temporary increase in IOP is stated. They do not look at the possible damage to the optic disc / visual field defects by temporary IOP elevations. Also, nothing is mentioned about the duration of the temporary IOP elevations, anti-glaucomatous medication use, surgical interventions and the present status.

Also the prevalence of glaucoma in patients with anterior uveitis based on herpes (HSV and VZV) varies greatly, these numbers are between 2 and 21%. The reported values **regarding the IOP elevations during active uveitis are quite similar and vary from 47 to 51%.

Study objective

With this research we want to determine the prevalence of glaucoma and temporary IOP elevations in our own anterior uveitis population, with a clear definition of glaucoma and IOP elevation. We will study two groups of patients, all with anterior uveitis based on already known HLA-B27 positivity or herpetic (HSV / VZV) associated anterior uveitis. All patients are or were treated for uveitis in the UMCG in Groningen. We will study these two groups of patients because these two forms of anterior uveitis are, in our region, relatively frequent. It is known that the etiology of uveitis varies between different ethnic groups and countries, and even between regions in the same country.

After this study we hope to have obtained a better understanding of the course of IOP elevations and glaucoma in these two groups. We will look at the prevalence of glaucoma and at a possible relationship between glaucoma and the number of uveitis episodes and duration of active disease. After this we hope to know if these patients, even after complete remission of the uveitis, have to be monitored for a possible development of glaucoma. We also want to know whether one or more ocular pressure peaks can cause damage to the optic nerve.

In addition to the occurence of IOP elevations and glaucoma, we will also look at the prevalence of other ocular complications. We will look at the formation of secondary cataract, posterior synechiae and cystoid macular edema. Also, the

visual acuity will be evaluated. We hope to gain more insight in preventing ocular complications in these two groups of patients.

Study design

The study has a retrospective study design. We will use patients* records to collect the data. The included patients receive a patient information letter about the study asking them to participate in the study to evaluate the present status.We will try, wherever possible, to combine the visit for the study with a scheduled visit at our clinic.

During the first visit we will investigate in all patients:
• The presence of any other ophthalmic disorder (such as cells in the anterior chamber and at the endothelium, iristransilluminatic defects of the iris, pseudoexfoliation, Krukenberg spindle, cataract) by slit lamp examination. To determine the presence of cataract or pseudoexfoliation, it is necessary to dilate the pupil with tropicamide.
• IOP measurement (applanation tonometry).
• The thickness of the nerve fiber layer of the retina (by laser polarimetry (GDx)).
• Visual field defects by perimetry (using Frequency Doubling Technology (FDT)).
• The thickness of the cornea (pachymetry).
• The condition of the retina by using the Optos camera (especially for capturing any retinal uveitic lesions or any other abnormalities that could explain visual field defects).

If it turns out that the first performed FDT is abnormal, a second FDT will be done. Is this one abnormal, then a more extensive perimetry will be performed by a Humphrey Field Analyzer (HFA). In case of abnormalities, this HFA will be performed three times. The average of the second and third measurement is a measure for the amount of detected damage. The patients in which the first or second FDT is normal, will only visit the clinic once. The patients who will perform one or more HFA's, have to repeatedly visit the clinic (with a maximum of three times). If the diagnosis of glaucoma is made**, a gonioscopy will be performed to view the anterior chamber angle. If a previous pachymetry is performed, then this needs not be done again. If a patient has performed perimetry before the start of the study, then we will check how this fits in our schedule and decide whether additional perimetry is necessary.

Performing an HFA and gonioscopy is standard medical care for glaucoma patients. We perform this additional testing only in patients who have indications for glaucoma (two times a positive FDT). If the diagnosis of glaucoma is made in a patient who is not already known with this, then one of the supervising ophthalmologists will be consulted about the necessary therapy and follow-up.

Study burden and risks

The risk that patients have and the load is minimal. The measurements performed during the first visit, will be conducted with ophthalmic equipment and are standard ophthalmological examinations. These measurements bring little risk and are normally also used in ophthalmic care. If patients have visual field defects on the FDT corresponding to glaucoma, a more extensive perimetry is needed. This does not increase the risk for the patient. Furthermore, only in patients suspected of glaucoma, gonioscopy should be performed. A lens will be placed on the eye, so we can look at the anatomy of the anterior chamber angle, this is necessary for making the correct diagnosis. We will anaesthetise the eye with a drop of Oxybuprocaïne. This examination provides no harm to the patient and it is a standard examination in patients with glaucoma.

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 anterior uveitis associated with herpes or HLA-B27.

Exclusion criteria

Patients whose cause of anterior uveitis is not certain.
Patients having more than one cause for anterior uveitis.
Patients with other forms of uveitis than anterior uveitis.
Patients who were already diagnosed with elevated IOP or glaucoma before the occurrence of uveitis.

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):	06-09-2012
Enrollment:	101
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL40195.042.12