VIFU (Visual Functioning in Uveitis patints)
Psychometric properties of the 25-Item National Eye Institute Visual Function Questionnaire (NEI-VFQ 25) in patients with autoimmune uveitis

Published: 24-08-2006
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The primary objective is to determine psychometric properties of the NEI-VFQ 25 in patients with uveitis, The secondary objectives will be to determine the impact of uveitis on the daily visual functioning of uveitis patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Eye disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29732

Source
ToetsingOnline

Brief title
VIFU

Condition

- Eye disorders

Synonym
arthritis of the eye, autoimmune ocular inflammation

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: aanvragen ingediend bij collectebusfondsen (ANVVB;LSBS;Oogfonds)

Intervention

Keyword: NEI-VFQ 25, SF-36, Uveitis, Visual Function Questionnaire

Outcome measures

Primary outcome

content validity

scale structure

internal consistency (cronbach alpha)

test- retest reliability (interclass correlation coefficient)

construct validity

responsiveness

(paragraph 7.4 protocol)

Secondary outcome

composite score NEI-VFQ 25

subscale scores NEI-VFQ 25

(paragraph 7.5 protocol)

Study description

Background summary

Uveitis is a chronic eye disease and an important cause of ocular morbidity.
Population based estimates of its true incidence and prevalence in the

Netherlands are unfortunately not available. Severe forms of uveitis often lead to visual impairment and blindness. In surveys of the causes of blindness uveitis is usually not included and is probably underestimated. The complications of uveitis like glaucoma, cataract and cystoid macular oedema are considered to be the direct cause, while the primary cause of the decrease in visual acuity (uveitis) is not mentioned.
We believe that for uveitis research it is important to find a method of measurement that emphasizes all different aspects of visual disability that patients identify as being important for their daily functioning. The traditional clinical measures of vision, such as Snellen visual acuity fail to assess many of these aspects, such as emotional well-being and social functioning. The review article of de Boer et al. revealed that the VCM1, the IVI and the NEI-VFQ 25 show the highest psychometric quality for people with visual impairments in general. From these three questionnaires the NEI- VFQ is the only one that encloses all four dimensions of quality of life (functional, social, psychological and physical).
The NEI-VFQ 25 is a widely used questionnaire that is tested for reliability and validity in patients with cataract, age related macular degeneration, diabetic retinopathy, primary open angle glaucoma, cytomegalovirus retinitis and low vision, but is not yet tested in uveitis patients..

Study objective

The primary objective is to determine psychometric properties of the NEI-VFQ 25 in patients with uveitis,
The secondary objectives will be to determine the impact of uveitis on the daily visual functioning of uveitis patients.

Study design

For this propective study we will recruite 300 patients from 7 European and 2 American sites and divide them into two groups, one with patients with acute and one with patients with chronic autoimmune uveitis due to one of the following causes: ocular sarcoidosis, intermediate uveitis, Behcet's syndrome, idiopathic retinal vasculitis, birdshot chorioretinopathy or Vogt-Kayanaki-Harada disease/ sympathetic opthalmia. The three different language groups in this study will be analysed separately to prevent bias due to translation differences.
Eligible participants will be asked to come for two visits (baseline and six month visit) on both visits they will undergo a complete ocular examination and will be asked to fill the SF-36 and the NEI-VFQ 25 questionnaire.
A subgroup of 30 patients will be asked to come for an extra visit between two to four weeks from baseline. This data will be used to test the test-retest reliability of the NEI-VFQ 25.

Study burden and risks

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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

1. Men and women *18 years with non-infectious uveitis due to one of the following causes: sarcoidosis, intermediate uveitis, Behcet's syndrome, idiopathic retinal vasculitis, birdshot chorioretinopathy, Vogt-Koyanaki-Harada disease or sympathetic ophthalmia, who meet the SUN criteria for acute uveitis.
2. Men and women *18 years with non-infectious uveitis due to one of the following causes: sarcoidosis, intermediate uveitis, Behcet's syndrome, idiopathic retinal vasculitis, birdshot chorioretinopathy, Vogt-Koyanaki-Harada disease or sympathetic ophthalmia, who meet the SUN criteria for chronic uveitis.

Exclusion criteria

Age < 18 years.
Inability to understand the questionnaire.
Inability to be seen 6 months after initial visit.
Inability to understand or sign the informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12297.018.06