Pathogenesis, diagnostics and complications of uveitis in childhood.

Published: 10-02-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Observational invasive

Summary

ID

NL-OMON33636

Source
ToetsingOnline

Brief title
Uveitis in childhood

Condition

- Anterior eye structural change, deposit and degeneration
- Autoimmune disorders

Synonym
inflammation of the uvea, intraocular inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: 1) Dr. F.P. Fischer-Stichting: Postbus 2756;3800 GJ Amersfoort;T 033-4552620;fischer.stichting@hetnet.nl De stichting heeft tot doel het bevorderen van de oogheelkunde. Zij tracht haar doel te bereiken door het verlenen

van geldelijke bijdragen ten behoeve van wetenschappelijk onderzoek;patiëntenzorg en opleiding op het terrein van de oogheelkunde en door het openstellen van haar wetenschappelijke collectie. 2) Stichting Nederlands Oogheelkundig Onderzoek (SNOO) Adrianaweg 14;6523 MV Nijmegen.

Intervention

Keyword: aqueous humor, child, juvenile idiopathic arthritis, uveitis

Outcome measures

Primary outcome

1. Protein profiles in the aqueous humor of children with non-infectious

uveitis.

2. Cells of the immune system in tissue fragments of iris and ciliary body of

children with uveitis.

3. Endothelial cell density (endothelial cell loss) in children with a glaucoma

implant (tube) for secondary glaucoma due to uveitis.

Secondary outcome

na

Study description

Background summary

Specific knowledge about cause and treatment of uveitis in childhood is for the present inadequately available in literature since uveitis in childhood is rare.

Study objective

First, to develop a diagnostic method for non-infectious uveitis in childhood. Second, to analyze iris and ciliary body tissues of children with uveitis on the presents of inflammatory infiltrate. The results of this study will contribute in the diagnostics of uveitis in childhood and in clarifying the pathogenesis of uveitis in childhood.

Third, to determine the long-term effect of glaucoma valve (tube) implantation on corneal endothelial cells in children with uveitis. The results of this study shall contribute to the better management of secundary glaucoma due to uveitis by children.

Study design

We will analyze the relation between protein profiles in the aqueous humor and the type of uveitis. Furthermore, tissue fragments of the iris and ciliary body of children with uveitis, who are operated on for secondary glaucoma, will be analyzed on the presence of inflammatory infiltrates. The tissue characteristics will be related to the cause of the intraocular inflammation and visual prognosis.
As third part of the study we will investigate and evaluate the long-term effects of glaucoma valve (tube) implantation in children with uveitis. The endothelial cell density will be prospectively evaluated by making of endothelialpictures once a year in children with a glaucoma implant and in a control group children with uveitis without the hystory of an eye opearation.

Study burden and risks

The treatment and therapy of the patients remains unchanged. Material will only be collected during a therapeutically necessary glaucoma or cataract surgery. Aqueous humor and possibly tissue fragments, which otherwise would be lost during surgery, will be collected. The cataract or glaucoma surgery will remain unchanged. When the child is under general anesthesia a venous punction (10ml) under sterile circumstances will be performed. The patient will not notice anything due to the anesthetics. The endothelial cell density will be measured once a year during 3 years in children with uveitis and a history of glaucoma surgery and children with uveitis without the hystory of glaucoma and eye opearation. Endothelial cell density measurement is painless and non-invasive. It takes about 5 minutes a time. During the measurement the child sits on a chair with his/ her chin on the chin-rest and looks at a green point. The device makes the picture of a corneal endothelial cells. This device does not make use of light or sound wich could scare a child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Uveitis diagnosed before the age of 16 years and cataract or glaucoma surgery

Exclusion criteria

uveitis diagnosed after the age of 16 years

Study design

Design

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

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2009
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	10-02-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25561.041.08