Long-term results of IOL implantation in paediatric patients
A patient registry

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To create a registry for paediatric patients with iris-fixated or posterior IOL*s, and the assessment of the long-term effects of implanted, artificial lenses in children.

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

Summary

ID

NL-OMON34502

Source
ToetsingOnline

Brief title
Artificial lenses in children

Condition

- Eye disorders NEC

Synonym
artificial IOL

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis

Intervention

Keyword: corneal endothelium, iris-fixated intraocular lens, patient registry, posterior 'in the bag' lens

Outcome measures

Primary outcome

Incidence of endothelial damage and endothelial cell density.

Secondary outcome

Vision.

Axial length of the eye.

Incidence of chronic anterior uveitis.

Study description

Background summary

In The Rotterdam Eye Hospital, paediatric patients with aphakia after surgery for lens luxation due to Marfan*s disease, homocysteinuria or ectopia lentis et pupillae receive an iris-fixated lens, while children with congenital or juvenile cataract receive a posterior, 'in the bag', intraocular lens (IOL). The relative proximity of iris-fixated lenses to the corneal endothelium may affect its condition, and thereby vision, in the long term. In this study data will be systematically collected to create a registry for paediatric patients with an artificial IOL.

Study objective

To create a registry for paediatric patients with iris-fixated or posterior IOL*s, and the
assessment of the long-term effects of implanted, artificial lenses in children.

Study design

Observational.

Study burden and risks

Participants do not benefit, risks are negligible, study procedures are non-invasive and take about 45 minutes extra time form patient and parent, annually.

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

Paediatric patients (4-15 years of age) with aphakia, iris-fixated or posterior IOLs.

Exclusion criteria

No informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2011
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL32307.078.10