Development of the infant eye following congenital and traumatic unilateral cataract.

Published: 20-12-2006
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Measurement of the growth of the eye of children with unilateral cataract.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital eye disorders (excl glaucoma)
Study type	Observational non invasive

Summary

ID

NL-OMON30226

Source
ToetsingOnline

Brief title
Eye development after cataract.

Condition

- Congenital eye disorders (excl glaucoma)

Synonym
cataract

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa.

Intervention

Keyword: critical period, development axial length eye, pediatric cataract

Outcome measures

Primary outcome

Significant difference in eye axis between experimental group and control.

Secondary outcome

Significant difference in eye axis between experimental groups.

Study description

Background summary

Developmental processes depend on internal as well as on external factors, with infancy (age upto eight years) being a critical period. Sensory deprivation, for instance, can affect the eye with respect to morphology and functioning. Cataract is diagnosed in children of various ages and standard treatment implies surgical removal of the affected lens. Depending on eye condition, an artificial Intra-Ocular Lens (IOL) may be inserted to replace the original one. Examination of developmental progress of the operated infant eye will increase knowledge of the underlying mechanism and time course of ocular maturation. This may help to improve the ophthalmologist*s assessment of best treatment and/or prospect of pediatric cataract.

Study objective

Measurement of the growth of the eye of children with unilateral cataract.

Study design

Retrospective, non-randomized.

Study burden and risks

This type of developmental research can only take place with children. Participants of this study do not benefit from the results of this study. Risks are negligible; burden comprises 1 visit of 30 minutes to the Rotterdam Eye Hospital.

Initial measurement of eye axis was performed by echo oculometry (requiring direct contact with the cornea) at the time of surgery and, thus, under anesthesia. Methodological consistency would be optimal if this measurement were repeated, but for ethical reasons (minimal discomfort for patients) and for practical reasons (maximal number of children cooperating) the second measurement will be done with a non-contact technique.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Informed consent.
- Unilateral congenital cataract.
- Unilateral traumatic cataract.
- Age < 6 years at the time of cataract surgery.
- If IOL implant not concurrent with cataract extraction: eye growth until implant.

Exclusion criteria

- Reluctance to cooperate.
- If IOL implant not concurrent with cataract extraction: eye growth since implant.

Study design

Design

Study type:	Observational non 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):	27-06-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2006
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	NL14857.078.06