

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Infant Aphakia Treatment Study (IATS)

This study is ongoing, but not recruiting participants.

Sponsor:

Emory University

Collaborators:

National Eye Institute (NEI)
Alcon Laboratories
Bausch & Lomb Incorporated
BSN-JOBST Inc.
Eye Care and Cure

Information provided by (Responsible Party):

Scott R Lambert, MD, Emory University

ClinicalTrials.gov Identifier:

NCT00212134

First received: September 13, 2005

Last updated: February 25, 2013

Last verified: February 2013

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Purpose

The primary purpose is to determine whether infants with a unilateral congenital cataract are more likely to develop better vision following cataract extraction surgery if they undergo primary implantation of an intraocular lens or if they are treated primarily with a contact lens. In addition, the study will compare the occurrence of postoperative complications and the degree of parental stress between the two treatments.

Condition	Intervention	Phase
Congenital Cataract	Device: optical correction of infant aphakia with Contact Lens or Intraocular Lens	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Infant Aphakia Treatment Study (IATS)

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Cataract](#) [Eye Wear](#)

[U.S. FDA Resources](#)

Further study details as provided by Emory University:

Primary Outcome Measures:

- Visual Acuity [Time Frame: 12 months of age and 4.5 years of age] [Designated as safety issue: No]
Visual acuity was measured by objective testing procedures at 12 months. There was no statistical difference in the vision in the study eye between the Contact lens and the IOL groups. Subjective VA measures will be done at 4.5 years.

Secondary Outcome Measures:

- Complications [Time Frame: 12 months of age and to 5 years of age] [Designated as safety issue: Yes]
There were more intra- and post-operative complications in the IOL group.
- Parenting Stress [Time Frame: 12 months of age and to 5 years.] [Designated as safety issue: No]

not yet published

Enrollment: 114
 Study Start Date: December 2004
 Estimated Study Completion Date: May 2014
 Primary Completion Date: January 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: aphakic contact lens optical correction of infant aphakia with aphakic Contact lens INTERVENTION: aphakic contact lens	Device: optical correction of infant aphakia with Contact Lens or Intraocular Lens optical correction of infant aphakia with Intraocular Lens or Contact lens Other Names: <ul style="list-style-type: none"> • Silsoft or RGP aphakic contact lenses • Alcon SA60 or MA60 silicon aphakic intraocular lens
Experimental: aphakic intraocular lens optical correction of infant aphakia with aphakic Intraocular Lens INTERVENTION: aphakic intraocular lens	Device: optical correction of infant aphakia with Contact Lens or Intraocular Lens optical correction of infant aphakia with Intraocular Lens or Contact lens Other Names: <ul style="list-style-type: none"> • Silsoft or RGP aphakic contact lenses • Alcon SA60 or MA60 silicon aphakic intraocular lens

Detailed Description:

Intraocular lenses are now a commonly accepted treatment for cataracts in older children and are used increasingly in younger children and infants. Intraocular lenses are superior to contact lenses in that they more closely replicate the optics of the crystalline lens, do not require daily ongoing care, and ensure at least a partial optical correction at all times. The simplicity and improved visual outcome of an intraocular lens correction may make caring for a child with a unilateral congenital cataract less stressful for parents. However, contact lenses remain the accepted treatment for children under 1 year of age due to concerns about the long-term safety of intraocular lenses and the potential for a large myopic shift developing in these eyes as they grow. Contact lenses provide excellent visual results in infants treated for bilateral congenital cataracts; however, two-thirds of infants treated with contact lenses for unilateral congenital cataracts remain legally blind in their aphakic eye. These poor visual outcomes are usually ascribed to competition from the sound eye and poor compliance with patching and contact lens wear regimens. Data from our pilot study and the literature suggest that superior visual results can be obtained if an intraocular lens is used to correct unilateral aphakia during infancy, but these eyes will experience more complications. Intraocular lenses will be increasingly implanted in infants regardless of whether or not we perform this trial. By performing this clinical trial, we can determine if the higher rate of complications with intraocular lenses is offset by improved visual outcome and decreased parenting stress.

The Infant Aphakia Treatment Study (IATS) is a multi-center randomized clinical trial comparing intraocular lens and contact lens correction for monocular aphakia. Infants will be enrolled over a 4 year period. Infants 28 to 210 days of age with a visually significant cataract in one eye are eligible. Cataract surgery will be performed in a standardized fashion by a surgeon who has been certified for the study. Surgery consists of a lensectomy, posterior capsulotomy, and anterior vitrectomy. Infants will be randomized at the time of surgery to one of two treatment groups. Infants randomized to the intraocular lens group will have an intraocular lens implanted into the capsular bag. Spectacles will subsequently be used to correct the residual refractive errors. Infants randomized to the contact lens group will be fitted with a contact lens immediately after surgery. Both groups will receive the same patching therapy and follow-up. All children will be examined by Investigators at fixed intervals using standard protocols with the major endpoint assessed at age 12 months by a Traveling Vision Examiner.

We are currently in a continuation of this project (beyond 5 years) in order to perform subjective visual acuity testing at 4.5 years of age and 5 year follow-up vision and ocular health exams on all children.

We will submit a competitive application to be able to have a single visit by the patients in this cohort when they reach 10 years of age. This will be past the amblyogenic period and permit a more accurate comparative assessment of visual acuity and ocular health between the primary intervention groups.

▶ Eligibility

Ages Eligible for Study: up to 210 Days
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Visually significant unilateral congenital cataract (central opacity equal to or greater than 3 mm in size).
- Cataract surgery performed when the patient is 28 to 210 days of age and at least 41 post-conceptual weeks.

Exclusion Criteria:

- The cataract is known to be acquired from trauma or as a side-effect of a treatment administered postnatally such as radiation or medical therapy.
- A corneal diameter less than 9 mm measured in the horizontal meridian using calipers.
- An intraocular pressure of 25 mm Hg or greater in the affected eye measured with a Perkins tonometer, tonopen, or pneumatonometer.
- Persistent fetal vasculature (PFV) causing stretching of the ciliary processes or a tractional retinal detachment.
- Active uveitis or signs suggestive of a previous episode of uveitis such as posterior synechiae or keratic precipitates.
- The child is the product of a pre-term pregnancy (<36 gestational weeks). Screening for prematurity will be based on the clinician's best assessment of gestational age. If a physician is uncertain regarding the gestational age, review of medical records or contact with the pediatrician and/or obstetrician should be used to confirm gestational age at delivery. Unless a clinician is uncertain as to whether a child was born at less than 36 weeks or not, confirmation of gestational age via medical record review may be delayed until after enrollment.
- Retinal disease that may limit the visual potential of the eye such as retinopathy of prematurity.
- Previous intraocular surgery.
- Optic nerve disease that may limit the visual potential of the eye such as optic nerve hypoplasia.
- The fellow eye has ocular disease that might reduce its visual potential.
- The child has a medical condition known to limit the ability to obtain visual acuity at 12 months or 4 years of age.
- Refusal by the Parent/Legal Guardian to sign an informed consent or to be randomized to one of the two treatment groups.
- Follow-up of the child is not feasible because the child would not be able to return for regular follow-up examinations and the outcome assessments (e.g. transportation difficulties, relocation, etc.).

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00212134

Locations

United States, Florida

Miami Children's Hospital
Miami, Florida, United States, 33155

United States, Georgia

Emory Eye Center
Atlanta, Georgia, United States, 30322

United States, Indiana

Indiana University Medical Center
Indianapolis, Indiana, United States, 46202-5175

United States, Massachusetts

Harvard University
Boston, Massachusetts, United States, 02115

United States, Minnesota

University of Minnesota
Minneapolis, Minnesota, United States, 55455-0501

United States, North Carolina

Duke University Eye Center
Durham, North Carolina, United States, 27710

United States, Ohio

Cleveland Clinic Foundation
Cleveland, Ohio, United States, 44195

United States, Oregon

Oregon Health and Science University
Portland, Oregon, United States, 97239-4197

United States, South Carolina

Medical University of South Carolina
Charleston, South Carolina, United States, 29425-2236

United States, Tennessee

Vanderbilt University

Nashville, Tennessee, United States, 37232-8808

United States, Texas

Pediatric Ophthalmology, P.A.
Dallas, Texas, United States, 75225
Baylor University
Houston, Texas, United States, 77030

Sponsors and Collaborators

Emory University
[National Eye Institute \(NEI\)](#)
Alcon Laboratories
Bausch & Lomb Incorporated
BSN-JOBST Inc.
Eye Care and Cure

Investigators

Study Chair: Scott Lambert, MD Emory University Eye Center

▶ More Information

Additional Information:

[NEI Clinical Studies Database—Infant Aphakia Treatment Study \(IATS\)](#) EXIT

No publications provided by Emory University

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

[Lambert SR, Lynn MJ, DuBois LG, Cotsonis GA, Hartmann EE, Wilson ME; Infant Aphakia Treatment Study Groups. Axial elongation following cataract surgery during the first year of life in the infant Aphakia Treatment Study. Invest Ophthalmol Vis Sci. 2012 Nov 7;53\(12\):7539-45. doi: 10.1167/iovs.12-10285.](#)

[Carrigan AK, DuBois LG, Becker ER, Lambert SR; Infant Aphakia Treatment Study Group. Cost of intraocular lens versus contact lens treatment after unilateral congenital cataract surgery: retrospective analysis at age 1 year. Ophthalmology. 2013 Jan;120\(1\):14-9. doi: 10.1016/j.ophtha.2012.07.049. Epub 2012 Oct 6. PubMed PMID: 23047003; PubMed Central PMCID: PMC3536935.](#)

[Drewe-Botsch CD, Celano M, Kruger S, Hartmann EE; Infant Aphakia Treatment Study. Adherence to occlusion therapy in the first six months of follow-up and visual acuity among participants in the Infant Aphakia Treatment Study \(IATS\). Invest Ophthalmol Vis Sci. 2012 Jun 5;53\(7\):3368-75. doi: 10.1167/iovs.11-8457.](#)

[VanderVeen DK, Nizam A, Lynn MJ, Bothun ED, McClatchey SK, Weakley DR, DuBois LG, Lambert SR; Infant Aphakia Treatment Study Group. Predictability of intraocular lens calculation and early refractive status: the Infant Aphakia Treatment Study. Arch Ophthalmol. 2012 Mar;130\(3\):293-9. doi: 10.1001/archophthalmol.2011.358.](#)

[Beck AD, Freedman SF, Lynn MJ, Bothun E, Neely DE, Lambert SR; Infant Aphakia Treatment Study Group. Glaucoma-related adverse events in the Infant Aphakia Treatment Study: 1-year results. Arch Ophthalmol. 2012 Mar;130\(3\):300-5. doi: 10.1001/archophthalmol.2011.347. Epub 2011 Nov 14.](#)

[Infant Aphakia Treatment Study Group, Lambert SR, Buckley EG, Drewe-Botsch C, DuBois L, Hartmann EE, Lynn MJ, Plager DA, Wilson ME. A randomized clinical trial comparing contact lens with intraocular lens correction of monocular aphakia during infancy: grating acuity and adverse events at age 1 year. Arch Ophthalmol. 2010 Jul;128\(7\):810-8. doi: 10.1001/archophthalmol.2010.101. Epub 2010 May 10.](#)

[Infant Aphakia Treatment Study Group, Lambert SR, Buckley EG, Drewe-Botsch C, DuBois L, Hartmann E, Lynn MJ, Plager DA, Wilson ME. The infant aphakia treatment study: design and clinical measures at enrollment. Arch Ophthalmol. 2010 Jan;128\(1\):21-7. doi: 10.1001/archophthalmol.2009.350.](#)

Responsible Party: Scott R Lambert, MD, Professor, Emory University
ClinicalTrials.gov Identifier: [NCT00212134](#) [History of Changes](#)
Other Study ID Numbers: NEI-108, U10EY013272, EY013287, EY013272
Study First Received: September 13, 2005
Last Updated: February 25, 2013
Health Authority: United States: Federal Government
United States: Food and Drug Administration

Keywords provided by Emory University:

cataract surgery
intraocular lens
contact lens
infants
aphakia

Additional relevant MeSH terms:

Aphakia
Cataract
Lens Diseases
Eye Diseases

ClinicalTrials.gov processed this record on March 23, 2014