

Information for Parents:
Avastin® Therapy for Retinopathy of Prematurity (ROP)
Children's Hospital & Research Center Oakland
Newborn Intensive Care Unit

What is retinopathy of prematurity (ROP)?

Retinopathy of prematurity (ROP) is a disorder of the blood vessels of the retina that affects extremely premature babies. The retina is the layer of nerve tissue that covers the inside and back of the eye and allows us to see. In premature babies, the retina is not fully developed at birth and can develop abnormally over the first few months of life. This abnormality is called retinopathy of prematurity. In babies with ROP the blood vessels of the retina stop growing, then begin to grow abnormally. These abnormal blood vessels may lead to scarring of the retina. In severe cases, scarring may pull the retina away from the rest of the eye, causing retinal detachment. Retinal detachment in babies with ROP often results in severe eye damage and permanent blindness.

How is ROP diagnosed?

Timely diagnosis is important in treatment of ROP. Your baby has received routine eye examinations by a pediatric eye doctor to monitor for development of ROP. The eye doctor can see ROP by looking into your baby's eyes.

What is laser treatment for ROP?

Until recently, babies who develop severe ROP have been treated with laser surgery. With laser surgery, a high intensity light is used to create small scars which help stop the growth of the abnormal vessels on the retina. These scars help control the growth of new blood vessels and reduce the risk of retinal detachment. In this way, the important central retina is protected. However, some peripheral vision may be permanently lost by the scarring.

What other alternative treatments are available for ROP?

Another treatment available for severe ROP is injection of Avastin® into the eye. Avastin® is a drug that works by blocking a substance known as vascular endothelial growth factor (VEGF), thus preventing the growth of new blood vessels. It is approved by the US Food and Drug Administration (FDA) for the treatment of some types of cancers. Once a medication is approved by the FDA, physicians may use it "off-label" to treat other diseases.

Ophthalmologists are using Avastin® "off label" to treat a number of other eye diseases. They have been using Avastin® for several years to treat adults with macular degeneration. More recently, they have started using Avastin® to treat some babies with ROP because Avastin® acts to block the production of one of the chemicals (VEGF) that causes abnormal blood vessel growth in ROP.

A new study published in the New England Journal of Medicine shows that injecting Avastin® into the eyes of premature babies with severe ROP may be even more effective than laser surgery and lead to shrinkage of the abnormal blood vessels in ROP. Not all babies who received Avastin® showed an improvement in their ROP. No severe systemic or local side effects were reported in these premature babies, although the studies were not designed to assess safety, and no data is available regarding long-term effects of Avastin in premature infants. More studies are necessary to determine short term and long term safety. Avastin® lasts for four to six weeks and appears to allow normal blood vessel growth in the eye to continue. Babies who receive Avastin® are followed closely by a pediatric or retinal eye doctor during their hospitalization and after hospital discharge.

How is Avastin® administered?

After the pupil is dilated and the eye is numbed with anesthesia, a topical antiseptic is used to sterilize the surface of the eye and the medication is injected into the main chamber of the eye as a single treatment. This is done in the Neonatal ICU.

What are the possible complications of Avastin® therapy?

When Avastin® is given to patients with cancer, some patients experience serious complications such as stroke, heart attack, hypertension, wound healing complications, bleeding, gastrointestinal complications, and congestive heart failure. Patients who had these complications were given 400 times the dose that babies with ROP receive, at frequent intervals, and in a way (intravenously) that spreads the drug throughout their bodies. Ophthalmologists believe that the risk of these complications for premature infants is very low because the drug is barely detectable in the blood after injection of such a tiny dose in the eye. In one study, patients treated with Avastin® injected into one eye did not have the serious problems occasionally seen in the patients with cancer. In the single study using Avastin® for premature babies, no systemic complications were seen.

What are the possible complications from the injection?

The possible complications of the injection of Avastin® include but are not limited to retinal tear, retinal detachment, damage to the cornea, bleeding, cataract, and glaucoma. Infection in the eye is a rare but potentially blinding complication. Eye drop medications may be given to try to reduce the possibility of complications.

Parent Consent:

Name of patient: _____

MR# _____

Date _____ Time _____

My child _____,

Has been examined directly by _____ on
_____(date) and has severe retinopathy of prematurity.

I acknowledge that Dr. _____ has described the above information to me in detail and in terms which I understand and has answered all questions I have asked about it to my satisfaction. He has explained significant complications and risks which may be associated with this procedure, and has advised me of possible alternatives to this treatment including the risks and complications associated with such alternatives.

I understand the potential risks, benefits, alternatives, and limitations of the treatment. I understand that Avastin® has not been approved by the FDA for the treatment of eye conditions. Nevertheless, I wish that my child receives treatment with Avastin® and I am willing to accept the potential risks and benefits as described above.

I authorize treatment for severe retinopathy of prematurity using Avastin® which will be injected directly into the _____ eye(s) to be performed by
_____.

Parent signature and date:

Witness signature and date:

Doctor's signature and date:
