

**Information for Parents:  
Avastin® Therapy for Retinopathy of Prematurity (ROP)  
UCSF Benioff Children's Hospital Oakland**

**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 weeks to months of life. This abnormality is called retinopathy of prematurity. In babies with ROP the blood vessels of the retina stop growing, then suddenly begin to grow too rapidly and abnormally. These abnormal blood vessels may leak and 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 results in severe eye damage and permanent blindness.

**How is ROP diagnosed?**

Early 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.

**How is ROP treated?**

Previously, babies who develop severe ROP have been treated with laser surgery. With laser surgery, a high intensity light is used to create small scars at the edge of the retina which stop the growth of the abnormal vessels on the retina. These scars seal the borders of the retina and usually eliminate the risk of retinal detachment. In this way, the blood vessels in the center of the retina are protected. However, some small amount of peripheral vision may be lost by the scarring.

**What other alternatives are available?**

Another treatment available for severe ROP is Avastin®. 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" in adults to treat some severe eye diseases such as diabetic eye disease and macular degeneration. More recently, there is increasing evidence to support its use for some babies with severe ROP because Avastin® acts to block the production of one of the chemicals (VEGF) that causes abnormal blood vessel growth in ROP.

A study published in the New England Journal of Medicine in 2010 showed that injecting Avastin® into the eyes of premature babies with severe ROP may be as effective as laser surgery and lead to shrinkage of the abnormal blood vessels in ROP. Treatment time was reduced using Avastin compared to laser surgery and there was less stress on the baby. Not all babies who received Avastin® showed an improvement in their ROP. No severe systemic or local side effects were reported in premature babies, but more studies are necessary to determine short term and long-term safety, because some Avastin® leaks into the baby's circulation, outside of the eye. Avastin® lasts for four to six weeks and allows normal blood vessel growth in the eye to continue. Babies who receive Avastin® are followed closely by a pediatric eye doctor during their hospitalization and after hospital discharge.

**Administration of Avastin®:**

After the pupil is dilated and the eye is numbed with anesthesia, a topical antibiotic solution is used to sterilize the surface of the eye, and then the medication is injected into the main chamber of the eye as a single treatment.

**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 is given to babies with ROP, 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 low, but the drug is 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 studies using Avastin® for premature babies, no systemic complications were seen.

**Complications from the injection:**

The possible complications of the injection of Avastin® include but are not limited to retinal tear, retinal detachment, damage to cornea, bleeding (cataract or glaucoma), and eye infection. Eye drop medications are given to reduce the possibility of these complications.

Parent Consent:

Name of patient: \_\_\_\_\_

MR# \_\_\_\_\_

Date \_\_\_\_\_ Hour \_\_\_\_\_

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  
\_\_\_\_\_.

I acknowledge that Dr. \_\_\_\_\_ has described the procedure to me in detail in terms which I understand and has answered all questions I have asked about it to my satisfaction.

Parent signature and date:  
\_\_\_\_\_

Witness signature and date:  
\_\_\_\_\_

Doctor's signature and date:  
\_\_\_\_\_