



THE OCULAR IMMUNOLOGY  
AND UVEITIS FOUNDATION

*Dedicated to Eye Disease Cure and Education*

**Allergan Posurdex Steroid Implant Study** This study tests different doses of the Posurdex steroid implant, which is given by injection in the office to the back of the eye (minor procedure, performed at MERSI) in patients with uveitis. The advantage of this is that the medicated pellet breaks down into carbon dioxide and water. This was a large international study, with over 80 participating sites across the world, including the US, Australia, the UK, South Africa. This study is closed and drug has come to market as Ozurdex.

#### **Denufosol Study**

This was designed to test the safety and efficacy of three doses of the novel molecule, denufosol, which stimulates certain receptors in the retina causing the retinal cells to 'pump' fluid out of the retina and eventually back into the bloodstream. In patients with macular edema, this drug stimulates the natural pump present in the retinal cells that for some reason stops working. The drug is given as two injections. This study is closed.

**EyeGate** EyeGate is the sponsor of a clinical trial where the study objective is to deliver an ophthalmic solution using the EyeGate® II Drug Delivery System in patients with non-infectious acute anterior segment uveitis. In this breakthrough concept, the drug (dexamethasone) is transmitted in a non-invasive manner by a non-painful electrical current. The creation of this delivery system was based on over 10 years of development. Four patients at MERSI have been treated using this innovative delivery system and we are now closed to enrollment. EyeGate is seeking regulatory approval of this delivery method in both the U.S. and Europe.

**Johnson & Johnson, Glaucoma Study** The goal of any treatment for glaucoma or ocular hypertension is reduction of IOP through the use of ocular hypotensive medications. Data from several recent research studies suggest that patients may receive a therapeutic effect from fewer doses of medication. Johnson & Johnson is conducting a new multicenter study of the safety and intraocular pressure (IOP) lowering effect of daily Lumigan (bimatoprost ophthalmic solution) 0.03% in patients with elevated intraocular pressure, when treatment is administered once every other day, or every third day as compared with the typical once daily dosing regimen. This study is closed.

#### **MUST Study**

The Multi-center Uveitis Steroid Treatment study across the USA funded by the National Institution of Health. The goal is to compare standard medical therapy (immunosuppressive pills taken by mouth) for uveitis with a recently approved steroid implant placed inside the eye (surgery), to see which therapy results in better control of uveitis, which therapy patients prefer, and which has fewer side effects. The steroid implant is the Retisert®, which was approved by the FDA in 2005. Dr. Foster was part of the original study that led to its approval, and some of our patients have had this treatment with good results. This study is closed and follow up study starting.

**Merrimack Pharmaceuticals Alpha Fetoprotein Study - finished** Alpha fetoprotein (AFP), a protein produced by a developing fetus present in the blood of pregnant woman. It has long been noted that uveitis and other autoimmune diseases improve during the later stages of pregnancy, when the levels of AFP rise. The inference is that this protein favorably affects the immune system, and pre clinical studies have supported this idea. Our study tests whether it is effective for sarcoidosis-associated uveitis and birdshot retinochoroidopathy. This study is closed and results were not favorable, but sample was small.

**Novartis** A new proof-of-concept study has been introduced to our site, sponsored by Novartis. The purpose of this study is to determine safety of AIN457 in patients with uveitis and to determine whether an antibody like AIN457 that neutralizes the cytokine IL-17A will safely reduce the intraocular inflammation associated with non-infectious uveitis. This study is closed.

**Novartis - AEB071** A new proof-of-concept study sponsored by Novartis, in which the purpose is to determine the safety and effectiveness of AEB071 in patients with uveitis. The study investigates whether an antibody like AEB071 that inhibits a category of enzymes called "Protein Kinase C" (PKC) can help to reduce macular edema associated with non-infectious intermediate uveitis, posterior uveitis, or panuveitis. This study is now closed to enrollment.

#### **Retisert steroid implant Study**

This study, originally started in 2001 was designed to test the safety and efficacy of the Retisert steroid implant that is implanted in the back of the eye and stays there, releasing steady amounts of corticosteroids over a period of two years. This has the advantage of not subjecting the patient to repeated injections. The study ended in October 2005, and Retisert is now FDA approved and on the market, available for purchase, as a result. Dr. Foster was one of the first ophthalmologists selected to test it, and it was placed in 25 of his patients.

#### **SITE Study**

This is also a multi center study across the US funded by National Institutes of Health(NIH), comprised of 5 different sites, but it is a chart review study and not a clinical trial. The goal is to determine whether the long term use of Systemic Immunosuppressive

Therapy for Eye diseases leads to a higher risk of malignancy or death. It is our understanding right now that it does not, but our current data is limited to one or two years. This study will definitely answer this question, which people have been asking since the introduction of such therapy in the late 1970s by Dr. Foster. The idea is to 'pool' together all the patients from the 5 biggest uveitis centers across the US, and to then analyze all of them together. The reason for taking such a large number of patients is to allow us to detect even a small increase in the development of cancer or malignancy. **The XIBROM™ Study** XIBROM™ is an ophthalmic, non-steroidal anti-inflammatory solution already FDA approved for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. It is currently manufactured and supplied by ISTA Pharmaceuticals, Inc. This study investigated XIBROM™ for effectiveness in treating the inflammation and pain associated with mild-moderate anterior uveitis.

**The Sirion Study** The purpose of this research study that Sirion Therapeutics is hosting is to see how safe and effective Difluprednate (Durezol) eye drops are as compared to Prednisolone Acetate eye drops in people with anterior uveitis. Dr Foster, who is also a member of the scientific advisory board for Sirion Therapeutics, remarks: "Difluprednate seems to represent an important advance in the fight against the potentially blinding consequences of severe uveitis. this study showed favorable response.