2. Austin January, 2024 **Clinical Research**

NEWSLETTER



ABOUT US

Austin Clinical Research (ACR) is a dedicated clinical research facility that conducts clinical trials for eve diseases. ACR conducts Phase I-IV clinical trials evaluating drug therapies and delivery devices for the following conditions:

- Dry and Wet Age-related Macular Degeneration (AMD)
- · Diabetic Retinopathy
- Retinal vein occlusions
- Uveitis
- Macular Telangiectasia Type II

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· Dry eyes



Patient Testimonial

"Because of ACR and the care I received I can still play softball. Everyone has been very good to me, they are like family and and have helped me maintain and improve my eyesight"

-Danny Leblanc (DR)

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January, 2024 **WHY** PARTICIPATE **IN A CLINICAL TRIAL?**

Participating in a clinical trial can be a deeply meaningful and altruistic endeavor, offering individuals the opportunity to contribute to the advancement of medical science and the development of treatments and therapies.

During the trial, you will receive specialized care and close monitoring from medical professionals who are dedicated to your well-being. In addition to the sense of fulfillment that comes from contributing to scientific progress, participating in a clinical trial can also offer hope for better health outcomes and a brighter future.

Your participation can make a difference not only in your own life but also in the lives of family members and countless others who may benefit from the knowledge gained through the trial. Moreover, clinical trials often provide access to cutting-edge therapies and medical care that might not be available through standard treatments.



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MEET OUR DOCTORS

BRIAN B. BERGER, MD



Dr. Brian B. Berger is the medical director at ACR. He has been the principal investigator in over 200 clinical trials. He attended the University of Chicago Medical School and completed his ophthalmology residency at the University of Illinois. During his career, Dr. Berger founded a medical and clinical research practice, published multiple articles and textbook chapters, and mentored many future doctors in his time in the field.

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FUAD MAKKOUK, MD



Dr. Fuad Makkouk is a highly skilled retina specialist with years of experience. He completed his medical degree at the University of Texas Medical Branch and a vitreoretinal surgery fellowship at Yale University before founding the Austin Eye Center. Dr. Makkouk is also actively involved in research studies aimed at improving the diagnosis and treatment of various eye diseases. In his free time, he enjoys exploring the outdoors with his wife, Diana.

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MEET OUR DOCTORS

ISAAC A. LOOSE, MD



Dr. Loose is a highly specialized ophthalmologist with a subspecialty in retina and vitreous diseases. He is a boardcertified professional with years of experience. Dr. Loose completed his medical education at the University of Texas Southwestern Medical School in Dallas, TX. He completed his residency at the Wills Eye Hospital in Philadelphia, PA, and a 2-year Retina/Vitreous Fellowship at Northwestern University in Chicago, IL. He is actively participating in several studies investigating macular degeneration, diabetic retinopathy, and retinal venous occlusions. Dr. Loose is a member of various medical associations.

STEPHEN B. WHITESIDE, MD



Dr. Stephen Bedford Whiteside is a native Texan and boardcertified ophthalmologist. He completed his medical training at Baylor College of Medicine and the Naval Aerospace Medical Institute. He has received numerous awards, including the Navy Achievement Medal and the Navy and Marine Corps Commendation Medal. Dr. Whiteside is an accomplished author and lecturer and has over a decade of experience as an investigator in clinical trials. He currently practices refractive surgery in Austin and serves as a consultant to the Army Warfighter Refractive Eye Surgery Program at Fort Hood.

BYRON D. BRENT, MD



Dr. Brent is a board-certified ophthalmologist specializing in retinal diseases. He completed his medical training at the University of Texas and has undergone additional training in retina and vitreous diseases and surgery, as well as excimer laser training. Dr. Brent is a diplomate of the American Board of Ophthalmology and a Fellow of the American Academy of Ophthalmology. Dr. Brent recently retired form his private practice in Austin and serves as an investigator at Austin Clinical Research.

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AGE-RELATED MACULAR DEGENERATION



FACTS ABOUT AMD

Currently, the underlying cause of macular degeneration remains unknown. However, this condition has been linked to various risk factors that can help predict if you fall into a group, making it more likely to develop AMD.

Some risk factors to keep in mind here include the following:

- Family history
- Smoking
- Age
- Hypertension (chronic high blood pressure)

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• White ethnicity

Macular degeneration is a common cause of irreversible vision loss in elderly individuals, particularly those of northern European ancestry. This progressive condition is linked to aging and tends to run in families. It affects the central area of the retina, known as the macula, which is responsible for color vision and reading. Although macular degeneration does not affect peripheral vision and does not lead to total blindness, it may make reading difficult and driving impossible in its advanced stages. Both eyes are always affected, and there is currently no cure for this condition.

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WET AGE-RELATED MACULAR DEGENERATION



Wet AMD when left untreated can result in leakage or bleeding of the vessels in the macula, resulting in blurred and distorted vision (pictured above in the far right)

The wet form of Macular Degeneration accounts for 10-20% of all cases and is characterized by a sudden onset of distorted and blurred vision in one eye due to leakage or bleeding in the macula. Early diagnosis is crucial, and currently available drugs have proven effective in maintaining or even improving vision when injected into the eye.

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However, these treatments are not cures and have to be administered regularly to maintain vision. Moreover, when one eye develops the wet form, there is a higher risk of the other eye developing the same condition at a rate of about 10% per year. Ongoing research is focused on reducing the frequency of treatments needed and improving the overall vision outcomes.

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DRY AGE-RELATED MACULAR DEGENERATION AND GEOGRAPHIC ATROPHY



Geographic Atrophy (GA)

More advanced forms of Dry AMD can lead to atrophy of the retinal tissue resulting in missing and darkened spots in vision (pictured above on the right)

AMD is most commonly classified as the "dry" form, which means that there is no bleeding or leakage in the retina. Compared to the wet form, dry AMD progresses much slower but can still lead to legal blindness. In the more advanced stages of dry AMD, loss of retinal tissue results in blind spots due to the formation of Geographic Atrophy (GA). GA is an area(s) of atrophy that forms in the macula, which is the center of your retina responsible for central vision.

In 2023, the first two treatments, Syfovre and Izervay, were FDA-approved for treating geographic atrophy (GA). These treatments inhibit an identified complement pathway, which is thought to lead to the formation of GA, and when injected into the eye monthly or every other month, they showed a modest slowing of GA progression with some potential

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treatment-related side effects. Despite treatments with these drugs, GA will continue to grow, and vision will continue to decline as a consequence. The variable and modest efficacy and potential safety concerns leave a remaining unmet need for new treatments for GA.

Regulatory approvals support the concept of complement inhibition in slowing the progression of GA. New dry AMD studies are evaluating the next generation of drugs targeting the complement pathway and other identified pathways with systemic administration of treatments, including pills and subcutaneous injections, as well as gene therapy delivered as a one-time injection. We are working to find potentially more effective treatments with fewer side effects.

To learn about our upcoming gene therapy trial for dry AMD, click <u>HERE.</u>

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NEW AND NOTEWORTHY



COGNITION THERAPUTICS

A new clinical trial is currently underway to examine the efficacy of a systemic medication (pill) for individuals who suffer from geographic atrophy (GA), a type of eye disorder caused by dry age-related macular degeneration (AMD). The study will include adults aged 50 and over who have been diagnosed with GA due to dry AMD. The trial's primary objective is to determine the safety and effectiveness of the systemic medication in slowing the progression of geographic atrophy. The study will involve 246 participants who will be randomly assigned to receive either the pill or a placebo. Participants will take the pill once a day for 104 weeks.

LEARN MORE

4DMT PRISM (WET AMD)

A clinical trial is being conducted to evaluate a new gene therapy for wet age-related macular degeneration (AMD) in adults. The trial involves testing different gene therapy doses and observing its effects on patients over time. The gene therapy is administered as a one-time injection into the eye in the office and is followed by 24 months of followup to evaluate efficacy and safety.

LEARN MORE

4DMT SPECTRA (DME)

This study aims to determine the safety and efficacy of a new gene therapy as a treatment for diabetic macular edema. The study will compare the effects of a single injection of 4D-150 gene therapy with the standard of care treatment, Eylea. The therapy will be administered through a one-time injection in the eye, and patients will be monitored for safety and efficacy over approximately 27

months.

LEARN MORE

Gene therapy has the potential to replace or significantly decrease the number of eye injections required to treat wet AMD and DME.

Please visit our website to learn more about our studies evaluating gene therapy.



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DIABETIC EYE DISEASE

DIABETIC RETINOPATHY

Diabetic retinopathy, caused by damage to the blood vessels in the retina due to diabetes, is a leading cause of vision loss among working-age Americans. Poor diabetic control and duration of diabetes increase the risk of developing diabetic retinopathy and other complications, such as diabetic neuropathy and kidney disease. Unfortunately, there is no cure for diabetic retinopathy, but treatments such as injections into the eye can slow its progression. It's important to get regular eye exams to detect early signs of diabetic retinopathy and get prompt treatment if necessary.

Our clinical trials are looking for more effective and longer-lasting treatments for diabetic eye disease. We are evaluating new drugs administered as eye injections or pills, as well as gene therapy options, which are administered as a single injection.



To slow the development of diabetic retinopathy: • Take your diabetes medicine as prescribed.

- Control blood sugar.
- Maintain healthy cholesterol levels.
 - Control blood pressure.

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CURRENTLY ENROLLING TRIALS

WET AGE-RELATED MACULAR DEGENERATION

- <u>Regenexbio RGX-314-3101 Ascent</u> A Phase 3 study evaluating a single administration of RGX-314 gene therapy compared to standard-of-care Eylea injections in patients with wet AMD
- <u>Regenexbio RGX-314-2104 Atmosphere</u> -A Phase 2b/3 study evaluating the efficacy of a single RGX-314 gene therapy compared to standard-of-care Lucentis injections in patients with wet AMD.
- <u>4D Molecular Therapeutics 4D-150-C001 Prism</u> A Phase 1/2 study evaluating a single injection of 4D-150 gene therapy compared to standard of care Eylea in patients with wet AMD.
- <u>Roche Burgundy</u> A study evaluating continuous delivery of a new drug delivered through an implanted device, port delivery system (PDS), compared to FDA-approved Lucentis delivered via the PDS. **ENROLLING SOON**

DIABETIC RETINOPATHY

• <u>Valo Health, Inc. OPL-0401-201 Spectra</u> – A Phase 2 study evaluating an oral agent, OPL-0401, in patients with diabetic retinopathy.

DIABETIC MACULAR EDEMA

- <u>Genentech ML43435</u> A Phase 3b/4 open-label study evaluating FDA-approved Faricimab in treatment naïve, underrepresented patients with diabetic macular edema.
- <u>4D Molecular Therapeutics 4D-150-C002 Spectra</u>- A Phase 2 study evaluating a single injection of 4D-150 gene therapy compared to standard of care Eylea in a patient with diabetic macular edema
- <u>Regenexbio RGX-314-2202 Altitude</u> A Phase 2 study assessing a novel treatment approach with RGX-314 Gene Therapy delivered via a single in-office injection in participants with diabetic retinopathy and macular edema.
- <u>Genentech GR43828</u> A phase I study of the efficacy of injections of a new drug alone or in combination with an FDA-approved drug in patients with diabetic macular edema.
- **<u>Roche Pregonda</u>** A Phase I study evaluating multiple doses of a new drug in patients with diabetic macular edema.

DRY AGE-RELATED MACULAR DEGENERATION

- <u>Genentech GE43220</u> A prospective, observational study of dry age-related macular degeneration progression.
- <u>Cognition COG2201</u> A Phase 2 study evaluating the efficacy of an oral agent for patients with geographic atrophy secondary to dry AMD
- Janssen JNJ-81201887 A Phase 2 study evaluating a single intravitreal administration of gene therapy compared to a sham procedure for the treatment of geographic atrophy secondary to AMD. ENROLLING SOON

MACULAR TELANGIETASIA

<u>Mactel NHOR</u> – A natural history, observation, and registry study of macular telangiectasia type 2.

<u>UVEITIS</u>

 <u>Genentech GR44277 Meerkat</u> – A Phase 3 study evaluating a new medication for the treatment of uveitic macular edema.

TO LEARN MORE ABOUT OUR CURRENT CLINICAL TRIALS, CLICK THE NAME ABOVE OR CONTACT OUR OFFICE

