Austin Clinical Research NEWS

ABOUT US

Austin Clinical Research (ACR) is a dedicated clinical research facility that conducts clinical trials for retinal 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 eye disease
- Retinal vein occlusions
- Uveitis
- Macular Telangiectasia Type II
- Vitreomacular traction
- Dry eyes

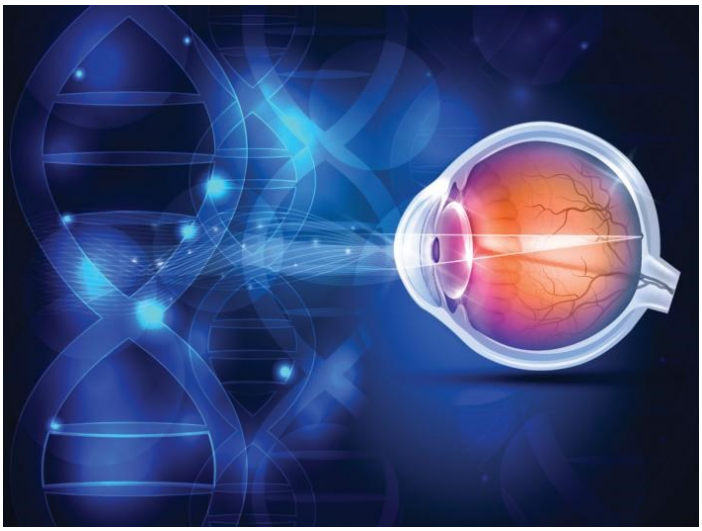
We strive to ensure that every patient is an optimal fit for a particular clinical trial, and is afforded unique, individualized care.

ACR has four board-certified physicians: Brian B. Berger, MD, Fuad Makkouk, MD, Byron David Brent, MD and Stephen B. Whiteside, MD. Our clinical research coordinators and photographers are certified, friendly, knowledgeable, and look forward to helping you and your family receive the latest treatments for retinal diseases.

We are located at 9707 Anderson Mill Rd., Suite 100, Austin, TX 78750

WHY PARTICIPATE IN CLINICAL TRIALS?

Clinical trials are at the heart of medical advances. They are designed to test novel approaches to preventing, detecting, and treating diseases. Trials evaluate next-generation drugs and look for new ways to utilize existing treatments, surgical procedures, and devices. Clinical trials offer cutting-edge treatment options that are potentially better than standard of care, in addition to the following benefits:



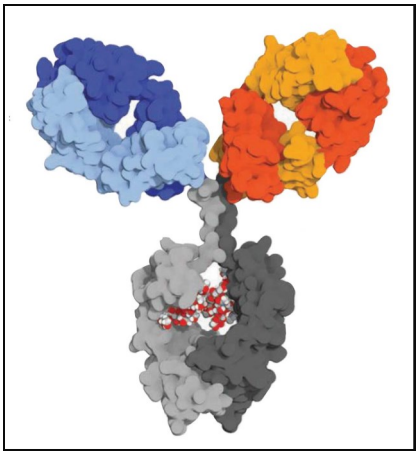
- Contribute to development of new treatments
- Receive a stipend for each completed visit
- Receive care for an eye condition for which an FDA approved treatment is not available
- Participation in a clinical trial is free of charge
- Transportation provided for all study visits
- Comprehensive eye care by board-certified ophthalmologists & experienced staff
- Dedicated coordinator throughout the study
- Snacks, coffee, and lunch provided for longer visits

TRIAL RESULTS

Collectively, the staff of Austin Clinical Research have participated in the development of all FDA-approved treatments for diseases of the retina. These collaborative efforts have resulted in FDA approval of new and better treatments. Over the past few years, our wonderful patients and staff contributed significant time and data, which has given rise to the approval of two new therapies for retinal diseases.

Genentech Vabysmo

Vabysmo, produced by the pharmaceutical company Genentech, is the first ever bispecific antibody for use in the eye. Vabysmo targets two disease pathways that are responsible for wet age-related macular degeneration (AMD) and diabetic macular edema (DME). Standard-of-care treatment for patients with AMD or DME includes eye injections administered every month or every two months. Clinical trials demonstrated that Vabysmo administered at intervals of up to **four months** either matched or induced better vision compared to patients treated with the current gold standard, Eylea, administered every two months. By extending intervals between eye injections, the burdens on both patients and healthcare providers can be alleviated. ACR staff and patients participated in this global study that brought a new generation of drug to the eye space.



Genentech Susvimo

Susvimo, produced by the pharmaceutical company Genentech, is a first-of-its-kind treatment method for wet age-related macular degeneration (AMD) that gives patients an alternative to standard-of-care monthly eye injections. Susvimo is a permanent refillable eye implant, approximately the size of a grain of rice. The device is pre-filled with a high concentration of Lucentis, an FDA-approved drug for wet AMD and placed in the eye by a retina surgeon in a minor out-patient procedure. Once placed, the Susvimo continuously releases Lucentis into the eye, eliminating the need for monthly injections.

In the Phase 3 clinical trials, patients that received the Susvimo demonstrated equivalent vision improvement compared to patients who received monthly standard-of-care eye injections. The device is refilled with new drug every six months with an in-office procedure comparable to a standard eye injection. The staff and patients at ACR contributed a substantial amount of data to this program with 29 patients enrolled in the clinical trials. This is a significant milestone for treatment of wet AMD **and we couldn't have done it without our WONDERFUL PARTICIPANTS!**

Genentech
A Member of the Roche Group

Kodiak DAZZLE

Austin Clinical Research participated in the Kodiak DAZZLE clinical study. The study did not meet the primary endpoint of showing non-inferior visual acuity gains compared to aflibercept given every eight weeks. However, nearly 60% of KSI-301 patients achieved every 5-month dosing at year 1 with visual acuity gains and anatomic improvements comparable to the overall aflibercept group. The study drug, KSI-301, was safe and well tolerated, with no new or unexpected safety signals.

DIABETIC EYE DISEASE

Diabetic retinopathy is the leading cause of blindness in American adults. High blood sugars cause damage to the blood vessels in the retina. The damaged vessels leak fluid and can result in swelling of the retina which leads to vision loss. Without treatment, diabetic retinopathy can progress to a more severe form in which new, abnormal blood vessels develop and bleed. Severe diabetic retinopathy can cause a significant visual impairment and may even require surgical intervention.

Patients with diabetic retinopathy may not have any symptoms or may experience the following:

Blurry Vision
Floaters
Missing Spots in Vision

AMERICAN DIABETES ASSOCIATION RECOMMENDS THAT ALL DIABETICS GET AN EYE EXAM AT LEAST ONCE PER YEAR TO MONITOR FOR DIABETIC EYE DISEASE.

EARLY DETECTION AND TREATMENT IS CRUCIAL TO MAINTAIN EYE SIGHT.

Normal Vision **Vision with Diabetic Retinopathy**

Diabetes is a life-long disease and requires constant treatment. The risk of developing diabetic retinopathy is related to length of diabetes and poor diabetic control. Eye injections are the most effective approved treatment, and are most commonly injected monthly or every other month. About 40% of patients with diabetic eye disease don't respond fully to current treatment. Research is aimed at finding new drugs that target new treatment pathways and last longer to reduce the frequency of treatment.

AGE-RELATED MACULAR DEGENERATION (AMD)

Age-related macular degeneration (AMD) is a chronic disease of the retina. It is the leading cause of irreversible vision loss in elderly Americans.

FACTS ABOUT AMD

- AMD always affects both eyes
- There is no cure for AMD
- AMD affects people age 50 or older
- AMD only affects central vision
- There are 2 forms of AMD:
  - Dry AMD
  - Wet AMD
- FDA approved treatments for wet AMD are available
- There is NO FDA approved treatment for dry AMD
- In its advanced forms, it can make it difficult to read and
- impossible to drive
- End-stage AMD results in total loss of central vision & legal blindness

Symptoms of AMD

- **Distortion**
- **Blind spots**
- **Blurry vision**
- **Dim vision**

Dry AMD

Most AMD is classified as the "dry" form. This label means that there is no associated bleeding or leakage in the retina. Eventual loss of retinal tissue can produce blind spots due to lesions called "geographic atrophy". Dry AMD progresses slower than wet AMD, but can ultimately lead to legal blindness.

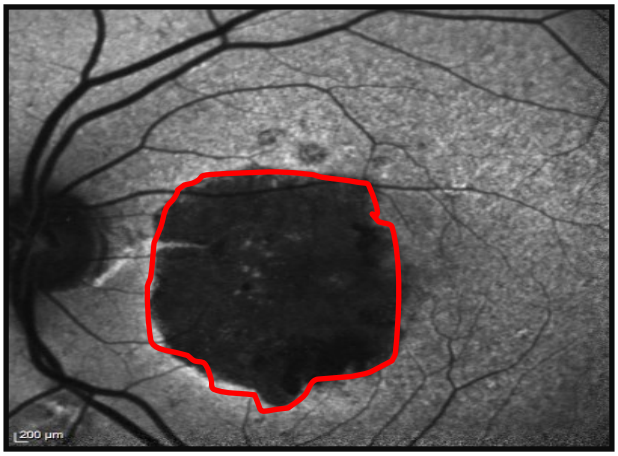


Image of a retina on the left. The dark spot circled in red is "geographic atrophy" which corresponds to a dark spot in central vision pictured in the image to the right.

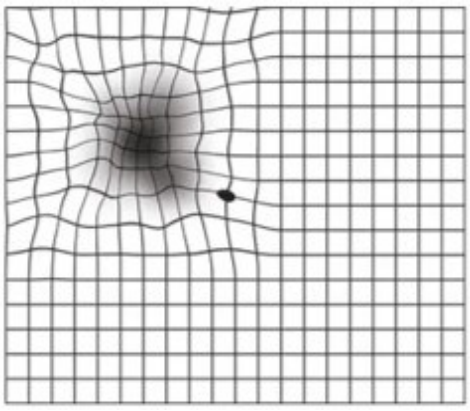
DRY AMD TREATMENT

Treatment is only available in a clinical trial. Current research is focused on slowing or stopping the progression of the disease and vision loss. To learn more about our enrolling trials, please visit: www.austinclinicalresearch.com

Wet AMD

What is Wet AMD?

About 10-20% of AMD is classified as the "wet" form. In this form, there is often a rapid onset of increased distortion and blurring of the vision in one eye due to leakage or bleeding from AMD. If diagnosed early, currently available drugs are quite effective in maintaining or improving vision when injected into the eye. These treatments are not a cure and must be continued indefinitely to maintain vision.



Wet AMD Clinical Trials

Current research is aimed at reducing the number of treatments and improving vision. Patients with AMD are encouraged to regularly check their vision with an Amsler grid, pictured above, which can help to determine if their condition has progressed to wet AMD.

Gene Therapy Trials for Wet AMD

In addition to clinical trials where patients receive standard intraocular injections, Austin Clinical Research participates in gene therapy trials for wet AMD. In these trials, patients receive a **one-time** gene therapy treatment at the start of the trial. Once the treatment is delivered to the eye, it behaves like a "drug factory", inducing continuous production of medicine that treats the wet AMD. The goal with gene therapy is to greatly reduce or even completely eliminate the need for regular injections. At this time, two gene therapy trials for the treatment of wet AMD are open for enrollment: "4D", sponsored by 4D Molecular Therapeutics, and "Atmosphere", sponsored by RegenXBio.

Patient Testimonial

"If I did not encounter the Austin Clinical Research team, I would be legally blind at this point. I was at the edge of when I walked into my first appointment with Dr. Berger. Thanks to the study inclusion, surgery, and wonderful care, I have 20/16 vision in my study eye and 20/25 in my fellow eye. They are very good at what they do and they CARE about the people they treat. None better anywhere."

- Larry Pope

Contact us to hear more about our enrolling gene therapy trials!

ASK OUR PATIENTS ABOUT PARTICIPATION IN TRIALS

Austin Clinical Research

Hours of Operation

Monday	8:00am—5:00pm
Tuesday	8:00am—5:00pm
Wednesday	8:00am—5:00pm
Thursday	8:00am—5:00pm
Friday	8:00am—5:00pm
Saturday	Closed
Sunday	Closed

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ENROLLING STUDIES FOR

WET AMD

DRY AMD

DIABETIC RETINOPATHY

DIABETIC MACULAR EDEMA

UVEITIS

MacTel TYPE II

TO SEE IF YOU QUALIFY, PLEASE EMAIL US OR VISIT WWW.AUSTINCLINICALRESEARCH.COM

Patient Interview

Charles Davis, wet macular degeneration

1). Please describe your experience with Austin Clinical Research during your trial participation. Why did you choose to participate in a clinical trial?

"I feel it is a great opportunity for myself and also to help future people as well."

What were the advantages of clinical trial participation?

"The chance to slow/stop the progression of my eye disease."

Were there any disadvantages to participation? If so, please elaborate.

"NO!"

Overall, would you say your experience was positive or negative?

"Very positive."

2). Would you participate in another trial with Austin Clinical Research?

"Yes."

3). Can you please address the stigma of "guinea pig" in relation to your experience with clinical trial participation?

"I do not feel like a guinea pig as I am receiving great quality care."

4). Can you please comment on the staff & doctors at Austin Clinical Research?

"Great atmosphere, great & caring physicians and staff."

5). Any other comments you would like to add?

"A pleasant experience at each visit."

ENROLLING TRIALS

Wet Age-Related Macular Degeneration

Roche BP40923 Bluetail: A Phase I study investigating injections of a new molecule, R07200394, in patients with neovascular AMD

Boehringer-Ingelheim 1336.0007: A Phase I, open label study assessing injections of a new drug, BI836880, in patients with wet AMD

4D Molecular Therapeutics: A Phase 1/2 trial evaluating 4D-150 Gene Therapy administered as a one-time eye injection in patients with wet AMD

Regenexbio RGX-314-2104 Atmosphere: A Phase 2b/3 Study evaluating RGX-314 Gene Therapy administered as a one-time eye injection in patients with wet AMD

Dry AMD - Geographic Atrophy (GA)

Genentech GR40973 Gallegos: A Phase II, sham-controlled study assessing intravitreal injections of a new medication, FHTR2163, in patients with geography atrophy

Ionis 696844-CS5: A Phase II, sham-controlled study evaluating multiple doses of IONIS-FB-L_{RX} administered subcutaneously in patients with geography atrophy

Genentech GR42163: A Phase I, open-label study evaluating a single injection of a new drug, RO7303359, in patients with geography atrophy

Alexion ALXN2040: A Phase II, placebo-controlled study evaluating an oral agent, Danicopan (ALXN2040), in patients with geographic atrophy

Genentech GE43220: A prospective observational study of the progression of intermediate age-related macular degeneration

Diabetic Retinopathy

Roche BP41321 Canberra: A Phase II placebo-controlled study investigating an oral agent, RG7774, for diabetic retinopathy with or without diabetic macular edema

Regenexbio RGX-314-2202 Altitude: A Phase II study evaluating efficacy of RGX-314 Gene Therapy delivered via a single injection in participants with diabetic retinopathy

Diabetic Macular Edema or Uveitis

Roche BP40899 Dovetail: A Phase I, open-label study investigating injections of a new molecule, RO7200220, in patients with diabetic macular edema or uveitic macular edema

Oxurion THR-149-002: A Phase II study to evaluate a new molecule, THR-149, targeting a new pathway compared to the standard-of-care, Eylea, in patients with diabetic macular edema

Genentech BP41783 Longitude: A longitudinal, biomarker study of Eylea to explore the relationship between aqueous humor composition and multimodal retinal imaging in patients with diabetic macular edema

Roche BP43445 Alluvium: A Phase II, double-masked study to investigate a new treatment pathway compared to standard-of-care Eylea in patients with diabetic macular edema

Genentech ML43435 Elevatum: A Phase IIIB/IV, open-label study to investigate Faricimab in treatment-naïve underrepresented patients with diabetic macular edema

Macular Telangiectasia

Mactel NHOR: A natural history observation and registry study of Macular Telangiectasia Type II

Current studies are evaluating new treatments that may be more effective and last longer, requiring less frequent injections. We also have studies evaluating oral medications and gene therapies as an alternative to injections. For more information about our enrolling trials, please visit our website:
www.austinclinicalresearch.com

OUR TEAM

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