

Ophthalmology Update

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Sophie J. Bakri, M.D.

Study Evaluates Potential One-Time Gene Therapy Treatment for Wet Age-Related Macular Degeneration

Neovascular age-related macular degeneration, also called wet age-related macular degeneration (wet AMD), is the most common cause of severe vision loss across the globe. The disease impacts close to 2 million people in the United States, Europe and Japan alone. In patients with wet AMD, newly formed leaky blood vessels in their retinas diminish vision over time.

Although anti-vascular endothelial growth factor (VEGF) therapies are the current standard of care to help prevent the progression of vision loss, these therapies require intravitreal injections that need to be repeated every 4 to 12 weeks for the rest of the patient's life — a rigorous treatment schedule that often can't be maintained for the long haul. As a result, as the treatment schedule lessens over time, so does the patient's ability to see.

Sophie J. Bakri, M.D., Ophthalmology at Mayo Clinic in Rochester, Minnesota, performed the first subretinal gene therapy at Mayo Clinic as part of a clinical study of RGX-314 as a potential one-time gene therapy for the treatment of wet AMD.

"This gene therapy is delivered surgically, by performing a pars plana vitrectomy and then injecting, under the retina, an AAV8 vector containing a gene encoding for a monoclonal antibody fragment," says Dr. Bakri. "The expressed protein is



designed to neutralize vascular endothelial growth factor (VEGF) activity. Anti-VEGF therapy is an established treatment for wet macular degeneration, but currently is delivered by repeated injections. Mayo Clinic is participating in this pivotal clinical trial, and we are pleased to offer this novel therapeutic to patients enrolled."

This randomized, partially masked Mayo Clinic clinical study will evaluate the safety and effectiveness of two dose levels of RGX-314 relative to monthly intravitreal ranibizumab injections. The primary endpoint of this study is mean change in best-corrected visual acuity (BCVA) of RGX-314 relative to ranibizumab. Approximately 300 participants who meet the criteria will be enrolled into one of three arms.

"This trial is important because it uses gene therapy to address an unmet need for the treatment of macular degeneration — reducing the burden of intravitreal

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injections on the patient and caregiver,” says Dr. Bakri. “There is hope that gene therapy could provide a one-time treatment for wet macular degeneration, and this trial will give us important information as to efficacy and safety.”

PARTICIPATION ELIGIBILITY

Participant eligibility includes age, gender, type and stage of disease, as well as previous treatment or health concerns. Guidelines differ from study to study, but all participants must be able to comply with all study procedures and be available for the duration of the study.

OBJECTIVES AND CRITERIA

The primary objective of this study is to evaluate mean change in best-corrected visual acuity (BCVA) of RGX-314 relative to ranibizumab at week 38, as well as the safety and patient tolerability of RGX-314 through week 102. Overall, this clinical study will evaluate:

- The effectiveness of RGX-314 relative to ranibizumab on BCVA.
- The effectiveness of RGX-314 relative to ranibizumab on central retinal thickness (CRT) as measured by spectral domain-ocular coherence tomography (SD-OCT).

- The effectiveness of RGX-314 relative to ranibizumab on center point thickness (CPT) as measured by SD-OCT.
- The need for supplemental anti-VEGF therapy in the RGX-314 treatment arms.
- Aqueous protein concentrations of RGX-314.
- The immunogenicity of RGX-314.

During phases 1 and 2 of this clinical study, researchers will assess the safety, side effects and optimal dosages, as well as the risks and benefits of this novel treatment. In phase 3, they will determine whether the treatment works better than the current standard therapy.

FOR MORE INFORMATION

A Study to Evaluate Gene Therapy to Treat Neovascular Age-Related Macular Degeneration. Mayo Clinic.

Mayo Clinic receives research funding for the Regenxbio clinical trial.

Dr. Bakri has served as a scientific advisor for AbbVie, Adverum, EyePoint, Novartis, Outlook Therapeutics, Ocular Therapeutix, Regeneron and Roche.

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Listen on your favorite podcast app.

By the Numbers: Mayo Clinic Ophthalmology Podcast

The Mayo Clinic Ophthalmology Podcast is hosted by Erick D. Bothun, M.D., and Andrea A. Tooley, M.D. Both are ophthalmologists at Mayo Clinic in Rochester, Minnesota. This podcast series covers the latest and greatest discoveries in ophthalmology through the lens of an academic institution, Mayo Clinic. Expert guests from around the world discuss ophthalmology and various subsets of the specialty. Recent topics of discussion include optic neuritis, pediatric cataracts, physician well-being, and more.

Audience

- 5,053 United States
- 391 Germany
- 349 United Kingdom
- 257 Canada
- 189 South Africa

8,317 All-time downloads

21 Number of podcast episodes

Top 3 Most Downloaded Episodes

1. **Physician Well-Being with Dr. Colin West (530 downloads)**
2. **The Future of Ophthalmology with vitreoretinal surgeon Dr. Sophie Bakri (514 downloads)**
3. **Financial Planning Tips for Ophthalmologists with Rosanna Boser (495 downloads)**

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Spotlight on Residents and Fellows



Mayo Clinic's Ophthalmology Residency aims to educate and inspire resident colleagues within a stimulating environment to learn the science and art of ophthalmology. Each year, four new residents are welcomed into the program, offering "an elite clinical training program with exceptional surgical training using Mayo Clinic's unique model of care," says Andrea A. Tooley, M.D., the Ophthalmology Residency director at Mayo Clinic in Rochester, Minnesota.

A variety of ophthalmology fellowship programs are offered at Mayo Clinic's campuses in Minnesota and Florida.

Fellowships include glaucoma, medical retina, neuro-ophthalmology, oculofacial plastic surgery, pediatric ophthalmology and strabismus, and retinal and vitreous surgery.

In addition to clinical care, Mayo Clinic Ophthalmology residents and fellows participate in innovative research, quality improvement, advocacy and educational opportunities.

Mayo Clinic Ophthalmology welcomes our latest PGY-1 resident class 2027 and congratulates our chief residents on their next endeavors.



Andrea A. Tooley, M.D.



Rachel N. Israilevich, M.D.
Hometown: Los Angeles
Medical School: Sidney Kimmel Medical College at Thomas Jefferson University



Kerri M. McInnis-Smith, M.D.
Hometown: Bozeman, MT
Medical School: Mayo Clinic Alix School of Medicine (Phoenix, AZ)



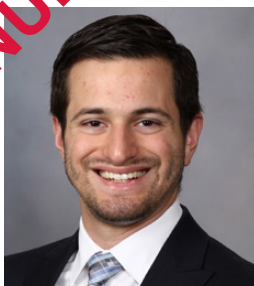
Grace Xiao, M.D.
Hometown: Vancouver, Canada
Medical School: Johns Hopkins University School of Medicine



Ashley Zhou, M.D.
Hometown: St. Petersburg, FL
Medical School: Johns Hopkins University School of Medicine



Beth C. Farazdaghi, M.D., is remaining at Mayo Clinic for a pediatric ophthalmology and strabismus fellowship.



Blake H. Fortes, M.D., is heading to the UCLA Stein Eye Institute for a surgical retina fellowship.



Ali R. Salman, M.D., is joining Retina Consultants of Minnesota for a surgical retina fellowship.



Saumya M. Shah, M.D., is going to USC Roski Eye Institute for a surgical retina fellowship.

Ophthalmology Conference Assembles Experts, Promotes Dialogue

The Mayo Clinic Ophthalmology Update 2023 provided an opportunity for ophthalmologists, optometrists, physicians, residents, fellows and scientist researcher Ph.D.s to connect and discuss comprehensive updates in ophthalmology and optometry for immediate clinical application.

The three-day live and livestream continuing medical education (CME) conference at The Ritz-Carlton Orlando, Grande Lakes, in Orlando, Florida, focused on a variety of topics across all subspecialties, including the evaluation and management of patients with macular degeneration, common eyelid, lacrimal and orbital disorders and appropriate management of patients with glaucoma.

“The Mayo Clinic Ophthalmology Update invites physicians, scientists and other ophthalmology health professionals to come together to learn new or updated treatment guidelines and examine relevant, essential topics that will benefit their practice,” says Sophie J. Bakri, M.D., chair of Ophthalmology at Mayo Clinic in Rochester, Minnesota.

Course directors included Dr. Bakri Joanne F. Shen, M.D., chair of Ophthalmology at Mayo Clinic in Phoenix/Scottsdale, Arizona, and Michael W. Stewart, M.D., chair of Ophthalmology in Jacksonville, Florida. The conference featured speakers from all three Mayo Clinic Ophthalmology sites and included case presentations, multiple Q&A panels, networking and CME credits.



Joanne F. Shen, M.D.



Michael W. Stewart, M.D.

MAYO CLINIC OPHTHALMOLOGY UPDATE 2024

Feb. 23-25, 2024

Orlando, Fla., and livestream

The Mayo Clinic Ophthalmology Update 2024 conference will take place Feb. 23-25, 2024, at the JW Marriott Orlando Bonnet Creek Resort & Spa in Orlando, Florida. Experience the conference in person or choose the livestream option for your convenience. The conference offers comprehensive updates in ophthalmology and optometry and covers relevant topics, including retina, cornea and external disease, orbital surgery, and more. Register at <https://ce.mayo.edu>.

Contact Us

Mayo Clinic welcomes inquiries and referrals, and a request to a specific physician is not required to refer a patient.

Phoenix/Scottsdale, Arizona

866-629-6362

Jacksonville, Florida

800-634-1417

Rochester, Minnesota

800-533-1564

Resources

[mayoclinic.org/medical-professionals](https://www.mayoclinic.org/medical-professionals)

Clinical trials, CME, Grand Rounds, scientific videos and online referrals

Education Opportunities

Visit <https://ce.mayo.edu/ophthalmology>.

Call 800-323-2688

or email cme@mayo.edu.

Ophthalmology Update

Mayo Clinic Ophthalmology Update is written for physicians and should be relied upon for medical education purposes only. It does not provide a complete overview of the topics covered and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.

Medical Editors

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Cover Image

Human multicolored iris of the eye animation concept

Credit: CG Alex

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