

Mayo Clinic detective work shows possible side effect in macular degeneration drug

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Two major drug trials conclude there was little risk from a drug aimed at age-related macular degeneration. Yet a Mayo Clinic ophthalmologist began to note something concerning in some of her patients: an increase in pressure inside the eye. It led to a retrospective study and findings that will be presented at the American Academy of Ophthalmology in Orlando.

Sophie Bakri, M.D., had been treating patients in her clinic with Food and Drug Administration-approved ranibizumab ([Lucentis](#)), when she began noticing a change in some patients.

"I was treating patients and measuring pressures, and I was surprised to see that in some of these people, their intraocular pressure was higher, and they didn't have a diagnosis of glaucoma," Dr. Bakri says. "So, why did the pressure go up? Was it from the drug itself, or the actual injection? Is this real? You don't know if it's a fluke unless you go back and look at the clinical trials. I took a closer look at the pooled data."

Intraocular pressure (IOP) is a measure of fluid pressure inside the eye. Measured in millimeters of mercury (mm/Hg), IOP that is higher than normal or above baseline (higher than 21 mm/Hg) can indicate [glaucoma](#).

Data from the two clinical trials in many ways held the answers to Dr. Bakri's questions, but she found that knowing what to look for helps.

MARINA (Minimally Classic/Occult Trial of the Anti-Vascular Endothelial Growth Factor Antibody Ranibizumab in the Treatment of Neovascular Endothelial Age-Related Macular Degeneration) and ANCHOR (Anti-VEGF antibody for the treatment of predominantly classic Choroidal Neovascularization in Age-Related Macular Degeneration) evaluated drugs including Lucentis, for treatment of age-related and other forms of [macular degeneration](#) (AMD). Both were two-year studies with monthly injections of Lucentis, compared to a control group who did not receive the injection. Pooling the two studies, which followed the treatment of 1,125 eyes, Dr. Bakri was able to perform a more robust evaluation of IOP changes. Some patients received Lucentis and others unknowingly received "sham" or mimicked injections, or a laser treatment called verteporfin photodynamic therapy (PDT), which did not involve injection.

Dr. Bakri found what she suspected: a subset of patients had increased IOP.

"We still don't know if it goes up because of the drug or the pressure of the repeated monthly injections, or both," she says. The take-home finding: [intraocular pressure](#) should be monitored in eyes receiving ranibizumab.

"A greater proportion of eyes in the [ranibizumab](#) groups had IOP increases regardless of the presence or absence of pre-existing risk factors, such as history of glaucoma, suspicion of glaucoma, ocular hypertension or use of a glaucoma medication," Dr. Bakri says.

A small portion, 8 percent, of all eyes across treatment groups received glaucoma medications in the study. Importantly, none of the patients needed glaucoma surgery.

"Our analysis was surprising because the increase was so prevalent and

highly statistically significant," Dr. Bakri says. "Lucentis is an excellent drug that works very well, but if we use a drug, we gain long-term experience, and that's where side effects start showing up.

Provided by Mayo Clinic

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