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MaculaNEWS

save sight institute

Welcome to the latest edition of MaculaNEWS in which we will tell you more about the Clinical Trials Unit of the Macular Research Group.

In the past we have told you about the clinical trials that we design and conduct ourselves, these are called “Investigator-Initiated”. Now we would like to tell you about the trials we conduct with support from pharmaceutical companies, known as “sponsored studies”.

Sponsored studies are usually conducted in conjunction with other clinics throughout the world. We receive funding to undertake these studies, but particularly with the Australian dollar as strong as it is we can barely cover costs.

Clinical trials test new drugs, so to a certain extent patients might think they are “guinea pigs”, but in fact guinea pigs rarely benefit from the research that is done on them, whereas patients often do.

Studies have shown that patients in clinical trials do better than those who refuse them even if they get placebo (pretend treatment)!

Since all new drugs have to be tested in large clinical trials before they can be approved for general use, participation in a clinical trial is the only way to receive a drug before it is released.

You do not always receive the new drug, some people are allocated the existing treatment for comparison and you cannot choose which you get (neither can we) but we make sure that the comparison groups receive the best possible treatment that is available so that it is unlikely that people who join one of our studies will be worse off.

The good news is that clinical trials are free for participants.

I’d like to thank you for your interest in our work, and encourage you to stay in touch.

Professor Mark Gillies and the Macular Research Group.

Macular Telangiectasia (MacTel)

Idiopathic Juxtafoveal Macular Telangiectasia Type 2 (MacTel) is an uncommon degenerative condition of the macula.

MacTel refers to a curious, poorly understood condition in which the blood vessels around the central macula, or fovea, which become dilated and incompetent, like varicose veins.

While MacTel does not cause total blindness, it commonly causes slow loss of the central vision, which is required for reading and driving vision, over many years.

As a leading centre in the international MacTel Project, the Macular Research Group is hoping to commence a clinical trial of a potential new treatment early next year sponsored by the Lowy Medical Research Institute.

Age-Related Macular Degeneration

Advanced AMD alone results in up to 40,000 new cases of blindness in Australia each year. Around 15% of people over 50 years of age (approximately 750,000 Australians) have some early signs of AMD.

The prevalence of AMD rises with age, so that nearly two out of three people who reach the age of 90 will have early AMD, with one in four having loss of vision from late AMD.

Vision loss from advanced AMD is caused either by the “dry” form, in which loss of vision due to wasting of the degenerate macula is slow, or by a much more rapid and destructive process called “wet” AMD, in which new blood vessels invade and destroy the degenerating macula.

Wet AMD accounts for only 10% of cases of AMD yet results in 90% of the severe vision loss.

It was discovered around 15 years ago that the protein “Vascular Endothelial Growth Factor” (VEGF) is the major cause of bleeding and blood vessel leak in many macular diseases. Wet AMD is now treated routinely with injections of anti-VEGF drugs directly into the eye such as Lucentis and Avastin, often very successfully.

REACH Study

The REACH Study, which is currently enrolling patients, will compare a new anti VEGF drug with Lucentis for Wet Macular Degeneration.

This 8-month trial sponsored by Allergan Pharmaceuticals will establish whether the new drug lasts significantly longer so that fewer injections are needed.

Dry AMD is proving a much tougher nut to crack than wet AMD, but this and other studies that are planned will hopefully provide us with something that can slow the progress of dry AMD in future.

The ideal treatment for dry AMD, retinal regeneration with stem cells, is even optimistically something like 10 years away.

Our aim: to develop new treatments that reduce blindness from macular disease, through multi-disciplinary and patient-oriented world-class research.

Branch Retinal Vein Occlusion

Clotting of blood in a retinal vein is a relatively common condition that is called Retinal Vein Occlusion (RVO).

When a retinal vein is blocked, blood returning from the retina that is drained by the vein is held up, causing the retina to bleed and swell, a condition known as retinal oedema.

If the affected retinal vein drains the macula, then this is another cause of macular oedema that may respond to treatments that are also being tested for diabetic macular oedema.

Branch Retinal Vein Occlusion (BRVO) occurs when the obstruction is in a “branch” retinal vein instead of the central retinal vein (see below).

If the occluded vein does not drain the macula then the patient may not even know it is there. If the macula is involved then blurred vision develops which cannot be cleared with glasses. Retinal vein occlusion may improve without treatment but most eyes are left with moderate loss of vision if not treated.

The Brighter Study

Currently enrolling patients with BRVO for treatment with Lucentis, a VEGF inhibitor that has been used very successfully for wet AMD for over six years.

This two year study has three treatment arms. Lucentis injections alone, laser alone, or Lucentis injections in combinations with laser.

After six months patients allocated to laser alone or injections alone will have the option of adding the second

Diabetic Macular Oedema

Diabetic macular oedema (DMO), the commonest cause of loss of vision in people with diabetes, is caused by leaking retinal blood vessels with swelling of the central retina (macula).

One in ten people with diabetes will suffer some loss of vision from DMO during their life.

DMO traditionally has been treated with laser photocoagulation, which seals the leaking blood vessels in the macula, slowing the swelling that causes impaired vision.

Laser may not improve vision once it has become blurred but it can prevent it from worsening.

We have recently started to treat DMO with injections into the eye as we do for macular degeneration.

The VIVID DME Study

Sponsored by Bayer Pharmaceuticals, this is ongoing but no longer accepting patients. This 3 year study is comparing two different doses of VEGF-Trap injections to laser therapy. VEGF-Trap is a new VEGF inhibitor, like Lucentis or Avastin. VIVID will test whether VEGF-Trap lasts longer than these established drugs.

Study for a tablet treatment for DMO

While injections into the eye may be very effective, they must be given up to 4 weekly and they also occasionally cause side effects, some of which may be serious. A tablet that treated DMO effectively and more safely might be attractive to many patients. Such a drug, SB-480848 which has been evaluated as a treatment for hardening of the arteries (arteriosclerosis) is being tested in a 4 month study sponsored by GlaxoSmithKline Pharmaceuticals. This study is currently enrolling patients.

In the Pipeline

Clinical trials of (hopefully) better treatments for these major vision-threatening macular diseases are starting and finishing all the time in our Clinical Research Unit.

As one of the major international centres for testing new treatments, the Macular Research group has participated in 32 major drug company sponsored studies over the last 10 years.

The intensive international clinical research activity, most of which is sponsored by pharmaceutical companies, directed towards finding better treatments for macular diseases has produced some outstanding results, such as Lucentis for wet AMD, over the last 10 years.

Who knows where we will be in another 10 years?

treatment (either injections or laser).

This study will establish how best to combine Lucentis with laser treatment.

The BDP Study

Ongoing but is no longer enrolling patients. This one year study sponsored by Allergan Pharmaceuticals is comparing the effectiveness of injections into the eye of new steroid drug AGN208397 with an established slow release steroid implant “Ozurdex”.

Our Macular Research Group pioneered the use of steroids for macular oedema when we started testing “triamcinolone” 10 years ago, however these new drugs are safer since they were specifically made for use inside the eye. This study will test whether the new drug lasts even longer than Ozurdex, which would mean fewer injections for patients.

Central Retinal Vein Occlusion

Central Retinal Vein Occlusion (CRVO) tends to be more severe than Branch Retinal Vein Occlusion (BRVO) since the entire retinal circulation is affected. AGN208397 was also available to people with CRVO through the BDP study.

Currently we are offering patients with CRVO the chance to participate in the Crystal Study, which is similar to the Brighter study except that all people receive Lucentis without any other groups for comparison.

Donations to Macular Research Group

If you are in a position to help us continue our research please consider making a donation. You can contribute online (www.savesightinstitute.com) or return this form to at GPO Box 4337, Sydney NSW 2001 or fax (02) 9382 7372.

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Save Sight Institute is a complying Centre of The University of Sydney and is affiliated with Sydney Eye Hospital.

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Save Sight Institute is a not-for-profit organisation, its mission being 'New Knowledge Creation to Save Sight'. All research relies exclusively on external grants, donations and bequests.

Donations over $2.00 are tax deductible. Please call us or visit www.savesightinstitute.com for more information about how to help our researchers continue their sight-saving work.

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