10 YEARS:
10 STORIES OF IMPACT

CASE STUDY 10

Protecting against eye damage in T1D

Diabetic retinopathy (DR) is a common and challenging complication of type 1 diabetes (T1D). Current treatment methods are highly invasive, require specialist training and are only used in late-stage DR.

The Australian Type 1 Diabetes Clinical Research Network (T1DCRN) has funded a project to examine the safety and efficacy of an oral drug currently used for prevention of DR in people with type 2 diabetes (T2D). This world-leading trial could lead to approval of this safer and cheaper treatment which can also be used at earlier stages of DR in people with T1D.

Australian Type 1 Diabetes Clinical Research Network

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

WHAT PROBLEM DO WE NEED TO SOLVE?

Over time many people with T1D develop macrovascular complications such as cardiovascular disease and damage to small blood vessels (microvascular disease) leading to neuropathy and kidney disease. In extreme cases these complications can lead to amputations and blindness. Almost half of all adults with T1D have at least one long-term complication.[33]

One common complication is diabetic retinopathy (DR), which occurs when there is damage to blood vessels and nerves in the retina and can lead to vision loss and blindness. Worryingly, after 20 years of T1D, most people have some level of DR[34], even in those with well-managed blood glucose, cholesterol levels and blood pressure.

The current treatment for DR in T1D is highly invasive and takes the form of intraocular injections, steroid eye implants, eye surgery and laser treatment.

WHAT WAS FUNDED BY THE T1DCRN AND WHY?

The T1DCRN has funded a project to examine the safety and efficacy of an existing drug — fenofibrate — for its potential to slow the progression of DR in T1D.

Fenofibrate is already approved in Australia by the Therapeutic Goods Administration (TGA) for halting the progression of DR in type 2 diabetes (T2D) and existing retinopathy. Fenofibrate is an oral lipid-lowering drug, normally used to treat high triglycerides.

There is firm evidence that fenofibrate slows the progression of DR and reduces the need for laser procedures, intraocular injections, and eye surgery in T2D, although its precise action is complex and not fully understood.[35]

It is plausible that fenofibrate could act in a similar fashion in those with T1D as it does in preventing DR in T2D. However, direct evidence and a safety assessment is required prior to the potential approval of fenofibrate for use in T1D.

Recognising the significant impact of DR on the T1D community, JDRF granted $1.3 million of T1DCRN funding to the Fenofibrate And Microvascular Events in Type 1 diabetes Eye (FAME 1) clinical trial, led by **Professors Alicia Jenkins** (pictured below) and **Anthony Keech** at the University of Sydney.

The trial is currently recruiting 450 adults with T1D with early DR and will determine if once-daily fenofibrate tablets for at least three years can reduce DR progression, reduce damage to blood vessels and improve quality of life.

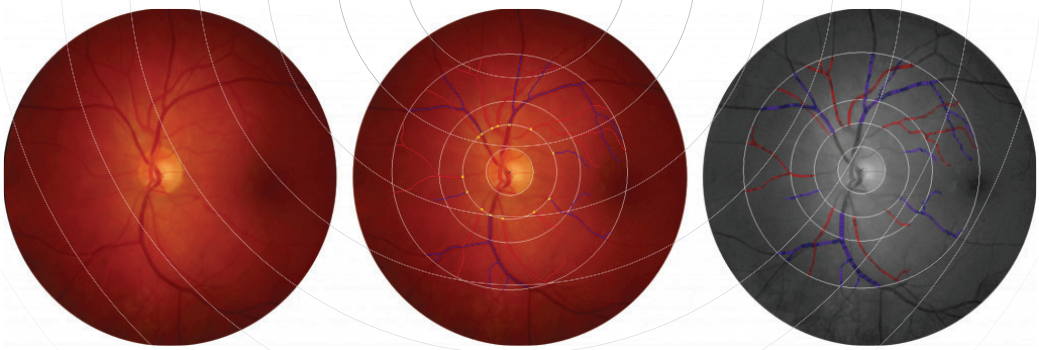
It is also expected that fenofibrate may protect against diabetes-related nerve and arterial damage and slow progression and induce some regression of nephropathy.

The trial, at the time of its approval, was a world first and involves 22 centres across Australia and New Zealand, with another two internationally (Hong Kong & Northern Ireland).

33. Accenture and JDRF. Economic Costs of Type 1 Diabetes in Australia. April 2021

34 Virk SA, et al. Interventions for Diabetic Retinopathy in Type 1 Diabetes: Systematic Review and Meta-Analysis. Am J Ophthalmol. Nov 2015;160(5):1055-1064.e4. doi:10.1016/j.ajo.2015.07.024

35 Sharma N, et al. The use of fenofibrate in the management of s with diabetic retinopathy: an evidence-based review. Australian family physician. 2015;44(6):367-370.



WHAT DOES THIS MEAN?

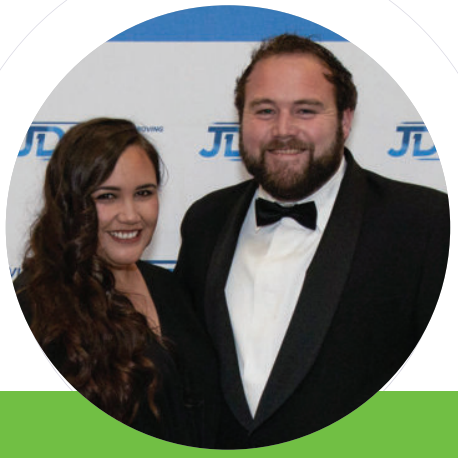
The results, if positive, would have significant impacts to the lives of those with T1D, as well as changes to clinical care.

Positive results would provide the needed evidence for TGA approval for the use of fenofibrate for preventing the progression of DR in those with T1D.

In turn, this would influence clinical practice recommendations for adults with T1D in Australia and internationally. For example, positive results could lead to changes to the NHMRC T1D guidelines and those from the Australian Diabetes Society, National Heart and National Kidney Foundations and similar overseas agencies.

Importantly, it would be ground-breaking for the T1D community. It would provide a DR treatment option which is less invasive and costly and associated with significantly less anxiety. Fenofibrate may also be of benefit for the early stages of DR.

Furthermore, at the clinical level, fenofibrate treatment would be expected to have wide take up, as it can be delivered by GPs and requires little specialty training, unlike the currently invasive treatments on offer for DR.



"DR is the first long-term complication I experienced from T1D. It was demoralising, confusing, and quite scary. I've already had two procedures to treat it: photocoagulation surgery, which is painful and incredibly stressful, and injections into my eyeballs, which cause me significant anxiety.

I really dread seeing my ophthalmologist in case I need further treatment, and I know that I will inevitably need a vitrectomy in both eyes. I take a lot of things to do with T1D in my stride but DR, its treatments and further complications cause me a lot of stress and worry about my future.

An alternative treatment that could slow the progression of DR would be incredible, especially if it was as simple as an oral tablet. It would improve my mental health and how I perceive my DR hugely.

Daniel Webb, who has T1D and DR, with partner Tara