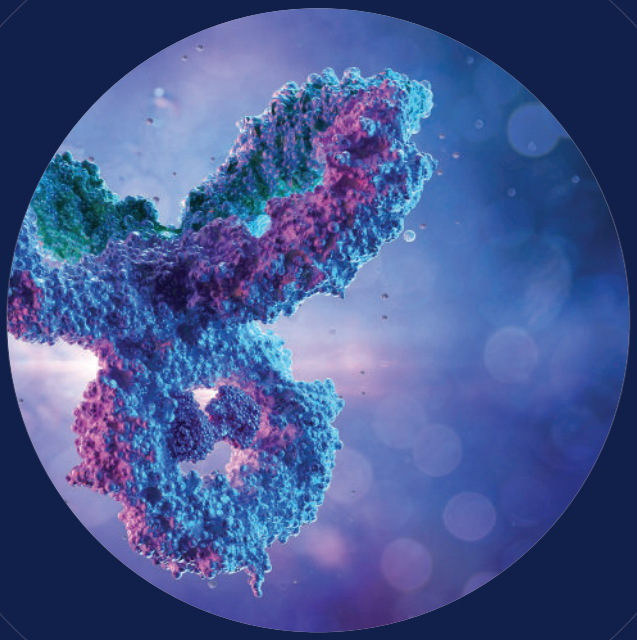

10 YEARS:
10 STORIES OF IMPACT

CASE STUDY 7

BANDIT: slowing down the destruction of beta cells

Often in those newly diagnosed with type 1 diabetes (T1D), there remains some level of beta cell function and thus insulin production. Using drugs to protect the remaining beta cells from immune system attack may help people to produce insulin for longer.

The Australian Type 1 Diabetes Clinical Research Network (T1DCRN) has funded a world-first trial to test a drug called baricitinib, currently used in rheumatoid arthritis, for its potential to protect residual beta cells in newly diagnosed individuals. Positive results of this trial would significantly change the T1D therapy landscape, adding another therapy to delay T1D progression in those newly diagnosed.

Australian Type 1 Diabetes Clinical Research Network

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

WHAT PROBLEM DO WE NEED TO SOLVE?

In people newly diagnosed with T1D, insulin initiation and stabilisation of blood glucose levels often leads to a 'honeymoon period' where the function of the remaining beta cells is recovered and insulin production is restored for a period of time. Using therapies that protect the remaining beta cells from immune system attack may help people to produce insulin for longer, with a range of consequent benefits.

WHAT WAS FUNDED BY THE T1DCRN, AND WHY?

For over 30 years, a team at St Vincent's Institute (SVI), led by **Professors Thomas Kay and Helen Thomas**, have been investigating the mechanisms in T1D that lead the immune system to attack beta cells.

Committed to finding new treatments for T1D, in 2020, JDRF awarded this team over $3.7 million in T1DCRN funding to undertake a clinical trial to test baricitinib, a drug which inhibits a signalling protein called Janus kinase (JAK) and which is currently used to treat rheumatoid arthritis.

This protein may be implicated in causing the inflammation and damage that immune cells illicit on beta cells during T1D. Therefore, inactivating JAK with baricitinib may protect beta cells from autoimmunity. The trial was called BANDIT (Baricitinib in New-Onset Type 1 Diabetes) and was the first trial in the world to test baricitinib in this way.

The SVI team had previously shown that baricitinib was able to delay T1D progression in pre-clinical studies, and the T1DCRN funding was critical to testing if this was also the case in newly diagnosed people with T1D. The significant T1DCRN investment in establishing ATIC infrastructure (case study 6) was key to allowing the BANDIT trial to proceed.

"It is tremendously exciting for us to be the first group anywhere in the world to test the efficacy of baricitinib as a potential T1D treatment. Our BANDIT study will determine if baricitinib can preserve beta cell function and insulin production in people recently diagnosed with T1D. This suggests that if given early enough, baricitinib may allow people with T1D to be significantly less dependent on insulin treatment.

Professor Thomas Kay, Principal Investigator, BANDIT trial

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It’s good to be part of this trial, to help researchers find new treatments for people with T1D. Participating has also been really helpful in having access to closer monitoring and support, via the clinical trial team, in the early stages of my diagnosis.

Lucy, first T1D participant signed up to the BANDIT trial, picture with BANDIT team member

WHAT DID THEY DO AND WHAT DID THEY FIND?

Recently completed, the BANDIT trial recruited 91 people aged 10 to 30 years who were newly diagnosed with T1D in the previous 100 days. The recruitment was at four sites across Australia and was completed in 15 months, six months ahead of schedule.

Participants were either provided baricitinib in tablet form daily for 48 weeks or a placebo. The trial primarily investigated the level of C-peptide (a marker of insulin production) over the 48 weeks. It also investigated the need for exogenous insulin, extent of glycaemic control via CGM and glycated haemoglobin levels (HbA1c; a marker of longer-term glycaemic control). The safety of baricitinib was also investigated.

WHAT DOES THIS MEAN?

The results of this trial are currently being analysed by the SVI team. If positive, these results would suggest that baricitinib can be used in those newly diagnosed with T1D to delay the progression of the condition. This in turn would allow people to minimise how much insulin they need to manage blood glucose levels.

Importantly, baricitinib could represent a new therapy option for newly-diagnosed T1D. Following approval by regulatory agencies, it could join the recently FDA-approved therapy, teplizumab, to delay T1D progression.