AUSTRALASIAN TYPE 1 DIABETES IMMUNOTHERAPY COLLABORATIVE

August 2024

ATIC Position statement on the use of baricitinib to treat type 1 diabetes

Background

In December 2023, ATIC investigators published results of a clinical trial involving 91 children and young adults aged 10 to 30 years who were within 100 days of type 1 diabetes diagnosis and shown to have residual beta cell function, defined as post-meal C-peptide greater than 0.2 nmol/l. Sixty participants received one year of baricitinib treatment as a daily 4mg tablet and 31 received matching placebo. Baricitinib treatment was associated with preservation of beta cell function, improved glucose control and decreased insulin use. The occurrence of adverse events and their severity did not differ significantly between treatment groups. Treatment was stopped after one year and trial outcomes for year two are awaited.

Thus, treatment for one year with baricitinib preserved beta cell function without major safety concerns in this relatively small study. Baricitinib decreased insulin requirements, but almost all participants still required some injected insulin and continued to monitor glucose at one year.

Some people with type 1 diabetes and residual beta cell function may be interested in taking baricitinib. Although baricitinib is approved for other indications and has been used in many thousands of patients, it has not been approved to treat type 1 diabetes. The ATIC consortium of type 1 diabetes researchers and doctors would at this stage recommend immune-based therapy to be used in settings where outcomes and adverse reactions can be systematically monitored. We consider it to be reasonable to consider off-label baricitinib therapy to preserve beta cell function in type 1 diabetes when these conditions are met. Similarly, people can be advised of currently available clinical trials suitable for them. The decision to administer baricitinib is best made by the affected individual and their treating doctor, who may wish to contact an ATIC researcher for guidance in its use. Health care facilities may require approval from their ethics and drug advisory committees to prescribe baricitinib for type 1 diabetes, especially for children.

Prescribing considerations:

If a decision to prescribe baricitinib has been made, we recommend the following:

- Before starting treatment, tests are performed to confirm the diagnosis of type 1 diabetes (i.e. islet autoantibodies) and the presence of residual beta cell function (e.g. fasting C-peptide >0.2nM)
- The patient is up to date with recommended vaccinations prior to starting baricitinib
- The patient or their doctor consider contacting ATIC (https://atic.svi.edu.au/get-in-touch/) to contribute their data to a national repository that aims to determine the effects of off-label treatment
- The treating doctor familiarise themselves with current prescribing information to ensure there are no contraindications to baricitinib, including pregnancy and breastfeeding
- The therapeutic effect is assessed after six months by measuring beta cell function (e.g. fasting C-peptide and glucose), insulin use, CGM metrics and HbA1c
- The decision to continue treatment will be guided by patient choice and the treating clinician's judgement; it is likely that treatment will need to continue to sustain any benefits observed. There is no data on treatment effect beyond one year's duration
- Doctors and patients should be aware that the BANDIT study showed that consistently taking the daily medication was needed to achieve and maintain beneficial effects.

An important consideration is cost. Baricitinib is approved for PBS use in rheumatoid arthritis and therefore each prescription costs $30 ($7 for concession card holders) but for "off-label" purposes it will cost significantly more. We are conscious that there may be some for whom the costs of "off-label" use are prohibitive and an alternative is to participate in an ATIC clinical trial.