A multi-centre trial of a new immunosuppression regime for pancreatic islet transplant recipients

ACTRN12619000268145

Status	RECRUITING
Phase	Phase 2
Sponsor	The University of Sydney
Enrollment	15 participants

Plain Language Summary

Type 1 diabetes can sometimes cause a dangerous condition called hypoglycaemia unawareness — where the body loses the ability to sense and respond to dangerously low blood sugar. For people with severe, recurring episodes that cannot be controlled through standard treatments, a pancreatic islet transplant (transplanting insulin-producing cells from a donor pancreas) can restore this awareness and reduce the need for insulin injections.

After a transplant, patients must take immunosuppressive medications for life to prevent the body from rejecting the new cells. This Phase 2 trial is testing a new combination of immunosuppressive drugs — belatacept and sirolimus — as an alternative to the standard regimen. The goal is to maintain transplant success while potentially causing fewer side effects, particularly for the kidneys.

You may be eligible if you have had Type 1 diabetes for more than five years, have severe recurrent low blood sugar episodes that don't respond to standard therapy, and meet specific health criteria including good kidney function and a weight under 85 kg. People with prior organ transplants, significant heart, liver or lung disease, HIV, hepatitis B or C, or a history of cancer (other than certain skin cancers) would not be eligible.

Key Eligibility Criteria

Inclusion (8)

- Subjects must be diagnosed with type 1 diabetes for more than 5 years.
- Subjects must, in the opinion of an endocrinologist, have severe recurrent episodes of hypoglycaemia not responsive to standard therapy.
- Subjects must have a calculated GFR greater than or equal to 75 mL/min/1.73 m2 (MDRD formula) at the time of enrolment (based on screening/baseline central laboratory results). They must have a serum creatinine greater than or equal to 130 µmol/L and a 24 hour urine protein estimation < 300 mg/day.
- Subjects must weigh less than 85 Kg
- Subjects must be EBV IgG positive

... and 3 more (see full listing online)

Exclusion (46)

-) WOCBP who are unwilling or unable to use an acceptable method of contraception to avoid pregnancy for the entire study period and for up to 8 weeks after the last dose of study medication. It should be noted that according to the US product information for mycophenolate mofetil (CellCept©) and mycophenolic acid (Myfortic©), “two reliable forms of contraception be used simultaneously unless abstinence is the chosen method”
-) WOCBP using a prohibited contraceptive method
-) Women who are pregnant or breastfeeding
-) Women with a positive pregnancy test on enrolment or prior to study drug administration
-) Subjects who had a positive T-cell or B-cell crossmatch

... and 41 more (see full listing online)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12619000268145

Locations (3 total)

Westmead Hospital - Westmead, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia
The Royal Adelaide Hospital - Adelaide, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia
St Vincent's Hospital (Melbourne) Ltd - Fitzroy, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia