Docket #: S23-270

A normothermic perfusion device combined with a stabilized form of WNT protein for organ rehabilitation prior to transplant

Clinician-scientists at Stanford have proposed a WNT formulation that, when used in combination with a first-of-its-kind normothermic perfusion device, reconditions marginal organs and enables their safe transplantation.

Each year, >100,000 people wait for organ transplant yet only 40,000 transplants are performed, leaving a waiting list of 60,000 patients with end-stage organ disease and no available options. A significant number of marginal organs are recovered but are not transplanted due to concerns of poor quality, suboptimal function, and limited regenerative capacity. What is critically needed to address this organ shortage are methods that allow for marginal organ rehabilitation, thus enabling them to be successfully transplanted without compromising patient outcomes.

There are two features of the proposed technology. The first is a perfusion device that mimics heart function, an oxygenator that mimics lung function, and a dialysis system that mimics kidney function. The second feature is the use of a novel perfusate additive, liposome-packaged human WNT protein (L-WNT). WNTs are potent stem cell activators that activate endogenous stem cells and enhance cell viability, thereby improving engraftment efficiency. The unique perfusion device loosens the narrow time constraints for transplantation, thereby allowing in-depth organ evaluation and clinical intervention. The use of L-WNT raises the possibility of functional liver reconditioning. Such a regenerative intervention has the potential to dramatically reduce organ shortages and in doing so, transform the organ transplantation landscape.

Stage of Development:

Normothermic perfusion device: in clinical development

L-WNT: GMP manufacturing complete

Applications

- Enable organ procurement organizations (responsible for donor management, organ retrieval, organ preservation, and organ transportation) to retrieve marginal organs and optimize them ex vivo prior to dispersal.
- Enhance hospital systems with organ transplant programs that are responsible for organ preservation, optimization, and transplantation into intended recipients.
- Support hospitals with major oncologic and hepatobiliary programs that offer major resections or ablations of partial liver for benign and oncologic conditions.

Advantages

- The technology ameliorates ischemia and reperfusion injury (IRI), thus reducing postoperative complications and their associated costs.
- The normothermic perfusion device with dialysis capabilities allows for sustained holding times, while the L-WNT perfusate additive enhances tissue repair and regeneration through its action on endogenous stem cells.
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