ORGAN TRANSPLANTATION - The Problem

The short-term success rates of transplant surgery have improved remarkably over the last half century, making this procedure a life-saving option for many patients with organ failure. Early outcomes in transplant recipients are outstanding: patients normally recover from surgery with a well-functioning replacement organ and typically return to an active lifestyle in a short period.

However, transplant practice is complicated by the immune reactions against allogeneic (non-self) tissues, resulting in donor organ destruction within a matter of weeks after transplantation. To impede this rigorous immunological response, an armamentarium of general immunosuppressive drugs has been developed. The concession of this therapeutic practice, in terms of safety and early recovery, is that the whole immune system is impaired and a myriad of side-effects are typical. Thus, patients after organ transplantation often suffer the consequences of drug toxicity, the development of chronic rejection, reduced resistance to infections and a high rate of cancer occurrence. Besides the morbidity associated with life-long immunosuppression, there are high financial costs for the families and for society to bear. Therefore, use of immunosuppressive drugs needs to be minimised.

ONE FOCUS

Preventing immunological rejection of transplanted organs without the need for long-term use of pharmacological immunosuppression is a primary objective in transplantation medicine. For this reason new transplant research should concentrate on early strategies that support long-term immunological acceptance of transplants, allowing for at least a reduction in the use of general immunosuppression. Conditioning the immune response of solid organ transplant recipients towards allograft acceptance using cell-based therapies is now becoming technically feasible and clinically promising.

The central focus of the ONE Study cooperative work programme is to:

- produce and manufacture distinct populations of haematopoietic immunoregulatory cells
- comparatively study the immunosuppressive characteristics of these regulatory cell types
- test these cell therapy products side-by-side in a clinical trial in living donor renal transplant recipients

The health economics of cell therapy as a new medical technology is another essential aspect of the ONE Study work programme that will be fully evaluated. True viability of the proposed new cellular treatments will depend not only on their clinical benefit, but also on an acceptable health-economics profile.

ONE DESIGN

The ONE Study consortium is presently made up of sixteen partners, of which ten are academic institutions and six are companies that support research. Six countries are represented: France, Italy, Germany, Switzerland, the United Kingdom, and the United States of America.

The coordinating centre in Regensburg has extensive experience in the conduct of large, complex, international, clinical trials in organ transplantation. All academic partners are internationally recognised groups with outstanding scientific backgrounds in the field of organ transplantation. Each participating partner has investigators with scientific expertise and the facilities to manufacture haematopoietic regulatory cells, and is locally affiliated with an experienced renal transplant program to test the cell therapy approach in our ONE Study clinical trial. The companies and SMEs allied in this study are committed to the advancement and commercialisation of cell therapy technologies.

ONE ALIANCE

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ONE OUTCOME

This very focused scientific research programme is expected to identify the most promising regulatory cell products for further clinical testing and commercial exploitation in the field of organ transplantation.

More generally, the anticipated scientific advances will also lead to a rationalisation of research efforts into cell-based techniques for the reduction of immunosuppressive drugs and will be potentially applicable for the treatment of other immunological conditions.
A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation

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