

The ONE Study

Re-educating the immune system

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After an organ transplant, a patient must take powerful drugs to suppress rejection of the new body part. The EU-funded **THE ONE STUDY** project is testing whether some of the body's own immune cells can improve organ acceptance. Initial clinical trials are underway.

Transplanting an organ from a donor into the body causes the recipient's immune system to react as this new organ is seen as 'different' to normal cells. The result is that the body's immune response against the new organ slowly damages the tissues and more than half of all grafts fail after 10 years.

Despite major advances in the field of immunosuppressive drugs, organ rejection following transplantation remains a serious problem. Moreover, side-effects of current therapies include increased risk of cancer and chronic infections. The answer, the Holy Grail of organ transplantation, is to prevent rejection altogether without using lifelong immunosuppressive drugs.

Cells fight back

THE ONE STUDY is aiming to develop a cell therapy to overcome organ rejection in the first place. "We are developing and growing populations of new cell types to put back in the body to suppress the rejection reaction," explains Edward Geissler, scientific project leader within **THE ONE STUDY**.

Ironically these suppressive cells are already part of the natural immune system. Their normal job is to regulate the immune reactions in the body and prevent an overboard response. "However, there aren't enough of them to tackle the rejection response so **THE ONE STUDY** is multiplying these cells and then putting them back in the patient," explains Geissler.

Interestingly, these immune cells can also pass on their tolerance to other similar cells, further enhancing the effect of the cell therapy. "This is a proven phenomenon and is called 'infectious tolerance'. Together with a reduction in rejection, this can be used to 'ramp up' immune regulation to further reduce rejection of the donated organ." he explains.

So far, the project has focused on establishing the necessary methods and protocols for cell production, using good manufacturing practice, at leading research institutions around the world. "A major part of the project is actually getting a licence to manufacture these cell products and obtaining regulatory approval," says Geissler.

Early clinical trial results promising

Using one single trial method (hence the name of the project), the cell therapy is being tested for safety and effectiveness on low to medium-risk kidney graft patients. Phase I of the trial is well underway in four European centres – in Germany, France and the United Kingdom – and in two US centres.

Each location is testing a particular immune cell type. All the data up to this point indicates that cell-based therapy for organ rejection is safe. So far, six cell products have been developed and licensed. The complete trial results are due in 2017. Once **THE ONE STUDY** finishes, the research can then progress to Phase II and III trials and move towards clinical application.

THE ONE STUDY is also creating lab methods to find out what happens when the cells suppress the body's immune response. These include a centralised immune monitoring programme to examine the suppressive effects of the most promising cells tested in the clinical trials.

Moreover, a new cell-tracking technology is being developed to follow the new cells in patients. The idea is to assess where the cells travel to and how long their journey takes. Geissler concludes: "The optimum outcome of this comprehensive programme is that the most promising cell therapy products will be tested in clinical trials on humans. The expectation is that cell therapy can ultimately reduce the need for immunosuppressive drugs in organ transplant recipients."

<http://ec.europa.eu/programmes/horizon2020/en/news/re-educating-immune-system>