

Clinical trial success for Crohn's disease cell therapy

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Speaking at the UK National Stem Cell Network annual science meeting later today, Professor Miguel Forte will describe research into a new cell therapy for chronic inflammatory conditions such as Crohn's disease. Patient's own blood cells are used to produce a type of cell – Type 1 T regulatory lymphocyte – that can reduce the extent of the disease.

Professor Forte said "T regulatory lymphocytes are amazing cells – they secrete proteins – cytokines - that dampen down the over active immune response that causes the terrible symptoms of chronic inflammatory diseases such as Crohn's. We know that treatments based on these cells can work but the challenge is to develop them in the clinic so as to maximise the benefits and minimise the risk. We must show that these cells are well tolerated and do a good job to treat the disease."

Professor Forte and his colleagues at TxCell in Valbonne, France, have used patient's own immune system cells derived from PBMCs – a type of blood cell – to treat patients with chronic inflammatory diseases like Crohn's disease. They used these cells, from patients with Crohn's, who had previously been treated with drugs and/or surgery but still had significant symptoms due to treatment resistance to make Type 1 regulatory T lymphocytes, which were then given back to the patients. The purpose of the study was to assess how well patients react in general to the treatment and also to check the efficacy of these cells for treating Crohn's disease. The preliminary results presented today show a good tolerability and, when given the correct dose, patients with severe Crohn's disease that do not respond to other treatments have an



improvement in their condition.

Cell therapy approaches, like this one and also MSCs, aim at using living cells as innovative new treatments to address unmet medical needs.

Professor Forte continued "It's still early days but the preliminary results are really good. The treatment didn't make the patients ill in any way and there is an early indication that their <u>Crohn's disease</u> has improved. The next step will be to do what we call a "phase 2b" clinical trial to find out if the treatment definitely works, what types of chronic inflammatory disease it works for, more about any potential side effects and how to manage them, and to confirm our results on the best dose used."

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