



New hope for patients as large-scale stem cell trials for osteoarthritis expected

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A large-scale clinical trial using adult stem cells to treat knee osteoarthritis is expected to be underway across Europe by the end of 2015. Almost EUR 6 million has been granted to the project 'ADIPOA-2' by the EU's Horizon 2020 research funding programme. The project will include 18 partners from Ireland, France, the UK, Germany, Italy and the Netherlands.

The Regenerative Medicine Institute (REMEDI) at the National University of Ireland Galway is coordinating the project.

Osteoarthritis is an incurable and debilitating disease. It has been identified as the world's eleventh highest contributor to disability and affects over 70 million Europeans. It causes severe and chronic pain, joint stiffness and loss of function. Currently there is no drug, medical intervention or therapy that alters the progression of osteoarthritis and many patients ultimately undergo total joint replacement surgery.

In its first phase, which completed in 2014, the EU consortium ADIPOA carried out a first-in-man Phase I safety study in 18 patients. Treatment involved a single injection of stem cells cultured from the patients' own fatty tissue. The results of this were sufficiently encouraging to warrant a larger, multi-centre Phase 2b study to further test the effectiveness of the treatment.

ADIPOA-2 will now build on the work of ADIPOA to deliver a randomised clinical trial across 10 hospitals in Europe involving 150 patients. The research will further assess the safety and efficacy of patient-derived stems cells in the treatment of advanced osteoarthritis of the knee.

Another major element of ADIPOA-2 will involve the production of consistent batches of high-quality autologous (patient's own) stem cells under GMP-compliant conditions. These cells will be produced in centres in France, Germany and Ireland. This multi-site approach will consolidate expertise in the preparation of clinically approved batches of stem cells across Europe in a ground-breaking cooperation between manufacturing centres.

Professor Frank Barry, Scientific Director of the Regenerative Medicine Institute (REMEDI) at the National University of Ireland Galway, is Coordinator of the ADIPOA-2 project. Professor Barry explains: 'The results from ADIPOA's first-in-man-trials were very encouraging and paved the way for another study to further test the safety and effectiveness on a wider scale. ADIPOA-2 is bringing together Europe's leading scientific, clinical and technical expertise on this project.'

Professor Christian Jorgensen, Head of The Clinical Unit for Osteoarticular Diseases University Hospital Montpellier in France, who led the Phase 1 trial and is Clinical Sponsor of the new trial, said 'Ambitious as it sounds, we are aiming to deliver an effective treatment for the debilitating and incurable condition of osteoarthritis within as little as five years. We have arrived at this point because of a great deal of work by many scientists, clinicians and stem cell experts who have made enormous contributions in understanding the therapeutic potential of stem cells.'

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