

Pioneering stem cell bandage receives approval for clinical trial

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Millions of people with knee injuries could benefit from a new type of stem cell bandage treatment if clinical trials are successful. The world's first clinical trial for the treatment of patients with torn meniscal cartilage has received approval from the UK regulatory agency, the MHRA1, to commence.

The current treatment for the majority of tears is the removal of the [meniscus](#), a procedure that often results in the early onset of [osteoarthritis](#).

The Phase I trial, one of the first in the UK to be approved using [stem cells](#), will treat meniscal tear patients with a cell bandage product, seeded with the patient's own, expanded, stem cells.

The cell bandage, produced by Azellon Ltd, a University of Bristol spin-out company, is focused on the research, development and commercialisation of an adult autologous (patient's own) stem cell technology which in vitro (tissue culture) has shown great promise for the healing of meniscal tears.

The trial is designed primarily to test the safety profile of Azellon's cell bandage in ten meniscal tear patients, but some information on whether or not it works will also be obtained. The bandage, containing the patient's own stem cells will be implanted in a simple surgical procedure using a specially designed instrument that helps to deliver the cells into the injured site as a first-line treatment in place of removal of the

meniscus. Patients will be closely monitored for safety over a five-year follow-up period.

Professor Anthony Hollander, Chief Scientific Officer at Azellon Ltd and Head of the School of Cellular and [Molecular Medicine](#) at the University of Bristol, said: "The approval we have received from the MHRA is an important milestone in the development of stem cell therapies in the UK. These cells hold much scientific and medical promise but we can only know if they work or not by testing them out in clinical trials."

Professor Ashley Blom, Professor of Orthopaedic Surgery at the University of Bristol, added: "The effective repair of meniscal tears would represent a significant advance in treatment, particularly for younger patients and athletes by reducing the likelihood of early onset osteoarthritis, and would offer an exciting new treatment option for surgeons."

More than 900,000 patients have meniscal tears every year in Europe with perhaps 800,000 to one million meniscal repairs in US making the total market 1.7 million meniscal tears per year. Seven per cent of meniscal surgeries are repairs in the 'red' zone, the rest (1,581,000 tears) remain total or partial menisectomies. Meniscus tears normally occur in active and younger people (estimated 80 per cent of meniscal patients are younger than 50). Meniscus tear is a common sports injury and is especially prevalent amongst competitive athletes in football (including US and Australian rules), rugby and basketball. Patients who have partial or total menisectomy have an increased risk of developing osteoarthritis over the following 4.5 to eight years.

Provided by University of Bristol

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