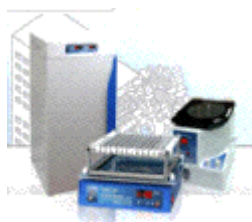


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Orthocell launches first clinical trial

 Tuesday, 12 August 2008
Nick Evans


PRIVATE Western Australian biotech company Orthocell will launch recruitment in the company's first human clinical trial of its tendon regenerative technology, after receiving ethics approval last week to conduct the trial in WA.

The company will trial its technology in a Phase 1/2a trial of 15–30 patients with recalcitrant tennis elbow.

Orthocell's tendon regenerative technology involves removing a small piece of tendon tissue from the patient and then culturing the cells over a period of weeks to amplify them to a level suitable for reimplantation.

Orthocell managing director Paul Anderson told *BTN* that, to the company's knowledge, the trial was the first in the human autologous tissue engineering approach towards tendon regeneration.

"So that's quite a step forward in the space, as well as for our company," he said.

Orthocell has been granted permission to access the public list for patients awaiting surgery on recalcitrant tennis elbow.

Anderson estimates that there are around 2500 patients on that waiting list in WA alone, and does not anticipate having trouble recruiting patients for the company's novel approach.

The trial's primary end points will measure the safety of the treatment, with secondary end points including relief from symptoms of tennis elbow and a reduction of tendon inflammation.

Anderson said he expects the trial will track safety data on the patients for 12 months, but the company has ethics approval to follow the patients for three years after implantation.

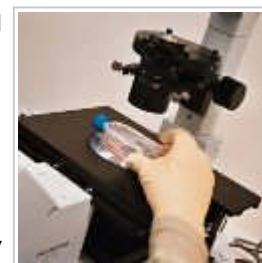
It is an important milestone for the WA company, which is one of the many life science companies that were waiting for a decision on a Commercial Ready application before moving ahead with their clinical program.

Anderson said the private company was always funded through to the end of the current clinical trial, but would now need to seek alternative funding for later stage clinical trials of the product.

Background notes

Orthocell's technology involves removing a small piece of tendon tissue from the patient and then culturing over a period of weeks before percutaneously implanting the new cells on the tendon tissue.

While Orthocell's initial trial is in recalcitrant tennis elbow, Anderson said the company's main clinical targets are rotator cuff injuries and Achilles tendon damage.



The company's intervention is targeted at serious ongoing problems – coming after the patient has tried remedial physiotherapy and perhaps after a single course of steroids, but before surgery is considered.

The company is also developing a novel collagen-based scaffold for use in tendon regeneration.



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