A double-blind randomized placebo-controlled phase IIb clinical trial to study the efficacy & safety of a Tendoncel™, a novel platelet lysate gel in the treatment of lateral epicondylitis (tennis elbow)

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Introduction: Lateral epicondylitis is a condition of the common insertion point of the extensor tendon. Currently there is little consensus regarding optimum treatment, several treatments, such as NSAIDs and steroid injections provide short term pain relief but do not affect the underlying pathophysiology. The condition affects 1% to 3% of the population leading to refractory tendinitis requiring surgery in 4 to 11% of patients. Recovery from surgery and time to return to normal function is typically 3-6 months. Growth factors derived from platelet lysate have been shown to facilitate healing in cutaneous and soft tissue injuries. Here we report on a Phase IIb trial investigating the efficacy and safety of Tendoncel™, a novel platelet lysate gel in the treatment of lateral epicondylitis.

Methods & Materials: 30 individuals, with a mean age of 51 years, 18 of whom were female, were randomized to either a treatment group with Tendoncel™, a patented topical platelet lysate gel, or control group with a physically identical placebo gel. The gels were applied once daily for 21 days with follow up over a period of 3 months. The efficacy was assessed using two functional questionnaires (DASH and PRTEE) and pain free grip strength. Tendoncel™ safety was monitored with standardized ADR reporting and assessed by a standardized participant questionnaire.

Results: The Tendoncel™ treatment cohort showed a statistically and clinically significant improvement in DASH and PTREE scores at 21 days of treatment (from baseline) compared to placebo control. Pain free grip strength was a secondary measure and was also statistically significant. There was no significant change in IgE levels. Tendoncel™ gel appeared safe and well tolerated.

Conclusion: Tendoncel™, a novel topical platelet lysate based therapy, is both efficacious and safe in the treatment of lateral epicondylitis.

Biography
Sabena Sultan is currently R&D Director at Cell Therapy Limited for 4 years. She is the British Heart Foundation Principal Investigator Grant Holder, Cardiovascular Medicine Department, Kings College London and Postdoctoral Scientist at Rayne Institute, Cardiovascular Medicine Department, University of London. She completed PhD in Cardiovascular Medicine, Imperial College School of Medicine.

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