



FACT SHEET

Clinical trial of investigational therapy for critical limb ischemia (CLI)

About the clinical trial: HemaTrate in the Treatment of Critical Limb Ischemia

- The first patient was enrolled and treated in the HemaTrate® CLI clinical trial by principal investigator Professor Bijan Modarai at Guy's and St. Thomas' Hospital, King's Health Partners, in London, UK, on August 27, 2019.
- The HemaTrate CLI (HT-CLI) trial is an international, randomized, controlled, multicenter study that will enroll up to 350 patients.
- Investigators interested in participating in the [HT-CLI pivotal trial \(NCT03809494\)](#) are encouraged to contact the study sponsor.
- Subjects with Rutherford class 4 or 5 CLI will be randomized to receive a series of three intramuscular injection treatments of total nucleated cells (TNCs) or saline, six weeks apart.
- The primary endpoint is clinical benefit through 12-month follow-up, defined as freedom from reintervention, major amputation, or death.
- The study will also evaluate safety and quality of life, and an analysis of predictive biomarkers will be performed on plasma samples from a subset of patients.
- Following the 12-month study period, all patients will be offered TNC treatment for both study and non-study limbs.
- Patients will be followed for a total of 24 months.

About the HemaTrate Blood Filtration System

- HemaTrate is a gravity-based blood filtration system used to generate autologous, total nucleated cell or platelet concentrates. The single-use system permits blood collection, concentrate preparation, and patient administration within a single outpatient office, interventional suite, or operating theater.
- The HemaTrate TNC output used in the CLI indication contains monocytes, lymphocytes, CD34+ hematopoietic stem/progenitor cells, basophils, neutrophils, and eosinophils, and is thought to exert its effects by releasing biologically relevant signals that stimulate tissue repair and regeneration.
- HemaTrate TNC concentrate is a regenerative technology with an overall profile that suggests use as a stand-alone or adjunctive treatment for CLI.

About peripheral arterial disease and critical limb ischemia

- Peripheral arterial disease is a narrowing of the peripheral arteries typically caused by atherosclerosis, which is the deposition of plaque in the arteries. Arterial narrowing (stenosis) reduces blood flow, thereby depriving affected tissues of oxygen and nutrients.
- Critical limb ischemia is the final stage of peripheral arterial disease and substantially reduces quality of life by causing pain and immobility, thereby interfering with daily activities.
- The leg ulcers characteristic of this disease frequently leads to amputation. Peripheral arterial disease that has progressed to CLI is often fatal even after the best available medical and surgical treatments.
- Approximately 30% of individuals with critical limb ischemia die within 1 year of surgical or medical treatment,¹ and approximately 40% die within 2 years of endovascular therapy.²



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About Cook Regentec

Cook Regentec is an Indianapolis-based company that develops the next generation of technologies for the preparation and delivery of biologic and therapeutic agents.

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1. Vircoulon M, Boulon C, Desormais I, et al. Comparison of one-year prognosis of patients classified as chronic critical lower limb ischaemia according to TASC II or European consensus definition in the COPART cohort. *Vasa*. 2015;44(3):220–228.
2. Soga Y, Iida O, Takahara M, et al. Two-year life expectancy in patients with critical limb ischemia. *JACC Cardiovasc Interv*. 2014;7(12):1444–1449.