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Stem cell therapy feasible, safe and beneficial for fistulizing Crohn's disease

Local injection of mesenchymal stromal cells (MSCs) has potential as a therapy for refractory fistulizing Crohn's disease, offering hope to patients who have this notoriously difficult to treat and disabling manifestation of Crohn's disease.

In their phase I–II trial, Rachel Ciccocioppo and colleagues harvested bone marrow and isolated MSCs from 12 patients—11 had actively draining complex perianal fistulas and one had numerous enterocutaneous fistulas. The MSCs were successfully expanded *ex vivo* (to at least 50×10^6 cells) and injected into the fistulas of 10 of the patients (two withdrew from the study). Injections were scheduled every 4 weeks, a median of four injections given and patients were followed up for 12 months (by clinical, surgical, endoscopic and MRI evaluation).

No treatment-related adverse effects were observed. Encouragingly, the researchers also found the treatment to be very effective. "All patients showed healing or reduction of fistula tracks and no recurrence was recorded within the 12-month follow-up period," explains Ciccocioppo. In addition, there was a significant and sustained increase in the percentage of mucosal and circulating regulatory T cells during the treatment and follow-up period.

"We believe that our study raises some fundamental points about the implementation of translational research in the field of gastrointestinal diseases and provides a direct link between bench and bedside," says Ciccocioppo. "We are confident, therefore, that this paper could inspire a large-scale randomized study."

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Original article Ciccocioppo, R. *et al.* Autologous bone marrow-derived mesenchymal stromal cells in the treatment of fistulising Crohn's disease. *Gut* doi:10.1136/gut.2010.214841 (2011)