

Mesenchymal stem cell therapy: All just rubbish?

Christianne Johanna Buskens

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Presentation

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The speaker argues that stem cell therapy for Crohn's fistulas is promising but has been poorly applied, with withdrawal of allogenic mesenchymal stem cells from the European market based on flawed trial design rather than true treatment failure.

KEY POINTS

- The speaker stated that the ADMIRE trial (212 patients) showed an 18% delta favouring mesenchymal stem cells at 52 weeks and led to European approval of Alofisel, while ADMIRE 2 (over 550 patients) showed no significant difference because the placebo group had unexpectedly high remission, leading to market withdrawal.
- Amsterdam data showed mesenchymal stem cells achieved comparable clinical and radiological healing to surgical closure in patients with a median of six previous interventions, versus one previous intervention in ADMIRE 2, suggesting patient selection was critical.
- Single cell analysis from the speaker's group found Crohn's fistulas exhibit high calprotectin expression in epithelial cells and disturbed wound healing compared to cryptoglandular fistulas, with calprotectin levels correlating directly with fistula severity class.
- The speaker reported that successful surgical closure occurred in patients with low fistula-tract calprotectin (around 100-250), while successful stem cell treatment occurred in patients with very high levels (around 6000), suggesting stem cells require inflammatory activation.
- The speaker stated autologous stromal vascular fraction is now used in daily practice, with Rotterdam pilot data showing 75% radiological healing at 3.7 years in 25 patients, though this contains hardly any actual stem cells.
- The speaker recommends focusing on understanding working mechanisms, stratifying patient selection based on fistula phenotype and inflammation rather than number of prior procedures, and conducting more trials before broad application.

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