Expanded adipose-derived stem cells for the treatment of complex perianal fistula: a phase II clinical trial.

Authors: Garcia-Olmo D, Herreros D, Pascual I, Pascual JA, Del-Valle E, Zorrilla J, De-La-Quintana P, Garcia-Arranz M, Pascual M

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Abstract:

PURPOSE: The feasibility and safety of stem cell-based therapy with expanded adipose-derived stem cells (ASCs) has been investigated in a phase I clinical trial. The present study was designed as a phase II multicenter, randomized controlled trial to further investigate the effectiveness and safety of ASCs in the treatment of complex perianal fistulas.

METHODS: Patients with complex perianal fistulas (cryptoglandular origin, n = 35; associated with Crohn's disease, n = 14) were randomly assigned to intralesional treatment with fibrin glue or fibrin glue plus 20 million ASCs. Fistula healing and quality of life (SF-12 questionnaire) were evaluated at eight weeks and one year. If healing was not seen at eight weeks, a second dose of fibrin glue or fibrin glue plus 40 million ASCs was administered.

RESULTS: Fistula healing was observed in 17 (71 percent) of 24 patients who received ASCs in addition to fibrin glue compared with 4 (16 percent) of 25 patients who received fibrin glue alone (relative risk for healing, 4.43; confidence interval, 1.74-11.27); $P < 0.001$). The proportion of patients with healing was similar in Crohn's and non-Crohn's subgroups. ASCs were also more effective than fibrin glue alone in patients with a suprasphincteric fistulous tract ($P = 0.001$). Quality of life scores were higher in patients who received ASCs than in those who received fibrin glue alone. At one year follow-up, the recurrence rate in patients treated with ASCs was 17.6 percent.

Both treatments were well tolerated.

CONCLUSION: Administration of expanded ASCs (20 to 60 million cells) in combination with fibrin glue is an effective and safe treatment for complex perianal fistula and appears to achieve higher rates of healing than fibrin glue alone.