

# Expanded allogeneic adipose-derived stem cells (eASCs) for the treatment of complex perianal fistula in Crohn's disease: results from a multicenter phase I/IIa clinical trial

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## Abstract

**Purpose** The management of perianal fistula in patients with Crohn's disease is an extremely challenging medical problem as many fistulas do not respond to available treatments. The objectives were to assess the safety and efficacy of a suspension of expanded adipose-derived allogeneic mesenchymal stem cells (eASCs) for the treatment of complex perianal fistula in Crohn's disease

**Methods** An open-label, single-arm clinical trial was conducted at six Spanish hospitals. Twenty-four patients were administered intralesionally with 20 million eASCs in one draining fistula tract. A subsequent administration of 40 million eASCs was performed if fistula closure was incomplete at week 12. Subjects were followed until week 24 after the initial administration.

**Results** Treatment-related adverse events did not indicate any clinical safety concerns after 6 months follow-up. The full analysis of efficacy data at week 24 showed 69.2 % of the patients with a reduction in the number of draining fistulas, 56.3 % of the patients achieved complete closure of the treated fistula achieved, and 30 % of the cases presenting complete closure of all existing fistula tracts. Of note, closure was strictly defined as: absence of suppuration through the external orifice and complete re-epithelization, plus absence of collections measured by magnetic resonance image scan (MRI). Furthermore, MRI Score of Severity showed statistically significant differences at week 12 with a marked reduction at week 24.

**Conclusions** Locally injected eASCs appear to be a simple, safe, and beneficial therapy for perianal fistula in Crohn's disease patients. Additional studies are needed to further confirm the efficacy of the eASCs.

**Keywords** Fistulizing Crohn's disease · Perianal fistula · Allogeneic adult stem cells

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## Introduction

Crohn's disease is characterized by an uncontrolled immune response to intestinal bacteria causing tissue damage which,