

Fecha: 28-10-2022

Asunto: Justification document for unposted
results of 2013-002015-98

European Medicines Agency
Orlyplein 24,
1043 DP Amsterdam,
The Netherlands

Dear EudraCT team,

Re: EudraCT - EudraCT results' document to be posted

Sponsor: Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias Avanzadas) – Fundación Progreso y Salud

The present trial has included a total of 27 patients out of the 51 expected by protocol. With active recruitment since February 2014, in February 2019 premature termination of the trial is reported due to extremely slow rate of recruitment. The interim analysis, carried out once the first 20 patients were recruited, yielded inconsistent results in terms of efficacy, and a new calculation of the sample size, which meant an increase in the "n" of the trial above the initial (n=57). This interim analysis was submitted to the Spanish National Competent Authority on the 14/05/2019. After assessing both aspects, and considering it unfeasible to reach the necessary sample size, the decision was made to end the clinical trial prematurely.

Various problems as a result of the pandemic, among them the lack of human resources, has complicated compliance with the deadlines established for the realization of the statistical report and the clinical report. We expect to send the summary of this clinical report to the competent authorities by the end of this current year.

EudraCT Number	Trial code - Full title of the trial	Sponsor name
2013-002015-98	CMMo/MD/2013 - Clinical trial phase III multicenter, double-blind, randomized, placebo-controlled trial evaluating the efficacy of intracoronary infusion of autologous adult stem mononuclear bone marrow unexpanded on functional recovery in patients with dilated cardiomyopathy and heart failure.	Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias Avanzadas) – Fundación Progreso y Salud

Fundación Progreso y Salud M.P.

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