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Please describe the contributions of each author, indicating who was responsible for each part of the study and the preparation of the manuscript (collection of data, experiments, data analysis, generation of figures, interpretation of data, preparation of the text, etc.) :

Responsible authors of the publication: Carlos Vallejo and Isidro Jarque
Isidro Jarque and Montserrat Batlle served as investigator coordinators of the trial. Lourdes Vazquez, Carlos Solano, Antonia Sampol, Rafael Duarte, Carlos Vallejo, Dolores Hernandez, Javier López, Montserrat Rovira, Santiago Jimenez and David Valcarcel served as investigators of the trial. Vicente Belloch interpreted the MRI analysis. Monica Jimenez supervised the execution of the study, and contributed to the analysis, interpretation, and reporting of the trial data. All authors contributed to the interpretation of data, reviewed and provided input into the manuscript and approved the final manuscript.