Unidad de Ensayos Clínicos
Agencia Española del Medicamento y Productos Sanitarios (AEMPS)
Parque Empresarial Las Mercedes, Edificio 8
C. Campezo, 1
28922 Madrid

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject	To state the reasons for the trial premature interruption
Study Title	Plasma Exchange in Patients With COVID-19 Disease and Invasive Mechanical Ventilation: a Randomized Controlled Trial
Protocol code	REP_COVID
EudraCT Number	2020-001722-66
Product	Albutein 5%®, Flebogamma DIF 5%® o 10%®
Sponsor	Fundació Clínic per a la Recerca Biomèdica
Trial end	29-Jun-2021

28th March 2025

Dear sir/madam,

The trial was a multicentre study conducted in Spain. This trial was approved by the Spanish authorities but ended prematurely. This study was not a Low Intervention Trial.

The active sites were:

- Hospital Clínic de Barcelona, C/ Villarroel 170, 08036 Barcelona
- Hospital de Bellvitge: C/ de la Feixa Llarga s/n, 08907 Hospitalet de Llobregat, Barcelona
- Hospital del Mar: Paseo Marítim Barceloneta, 25-29, 08003 Barcelona
- Hospital Germans Trias i Pujol: Carretera de Canyet s/n, 08916 Badalona, Barcelona
- Hospital Josep Trueta de Girona: Avenida de Francia s/n, 17007 Girona
- Hospital Universitario Virgen del Rocio: Avenida de Manuel Siurot s/n, 41013 Sevilla

Harmonised Protocol (SPAIN as a Member State):

Protocol (version, date)	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
2.0, 12-Apr-2020	23-Apr-2020	21-Apr-2020	CEIm Hospital Clínic de Barcelona
3.0, 05-Nov-2020	01-Feb-2021	25-Jan-2021	CEIm Hospital Clínic de Barcelona

Declaration:

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), hereby declares that the clinical trial with EudraCT Number 2020-001722-66 ended prematurely on 29-Jun-2021.

The reasons for the premature termination were:

- Not having reached the expected number of patients in the study
- Lack of funding to extend the study for a longer period

An interim analysis was planned upon reaching 30 patients, and this analysis has been completed with the following results:

Variable	**All patients**	**SMT**	**P. Exchange + Polyclonal immunoglobulin + SMT**	**pvalue**
TOTAL	30	15	15	.
Exitus at 28 days	6/30 (20.0 %)	3/15 (20.0 %)	3/15 (20.0 %)	1.0000
Follow-up at 28 days or Days to Death	(30) 28.00 (28.00 - 28.00)	(15) 28.00 (28.00 - 28.00)	(15) 28.00 (24.00 - 28.00)	0.6981
Exitus ICU	9/30 (30.0 %)	5/15 (33.3 %)	4/15 (26.7 %)	1.0000
Days in ICU or Days to Death	(30) 19.00 (11.00 - 40.00)	(15) 15.00 (10.00 - 36.00)	(15) 24.00 (12.00 - 42.00)	0.6077
Exitus Hospital	9/30 (30.0 %)	5/15 (33.3 %)	4/15 (26.7 %)	1.0000
Days in Hospital or Days to Death	(30) 34.50 (17.00 - 57.00)	(15) 35.00 (15.00 - 46.00)	(15) 34.00 (17.00 - 62.00)	1.0000
Exitus at 90 days	9/30 (30.0 %)	5/15 (33.3 %)	4/15 (26.7 %)	1.0000
Follow-up at 90 days or Days to Death	(30) 90.00 (36.00 - 90.00)	(15) 90.00 (36.00 - 90.00)	(15) 90.00 (24.00 - 90.00)	0.9609

Please do not hesitate in contacting us should you need further information.

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC