

**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 reasons for the trial premature interruption
Study Title	Treatment with inhaled corticoids in patients with COVID19 admitted to hospital with pneumonia
Protocol code	TACTIC-COVID
EudraCT Number	2020-001616-18
Product	PULMICORT® TURBUHALER® budesonide Dry Powder for Oral Inhalation 400 mcg
Sponsor	Fundació Clínic per a la Recerca Biomèdica
Trial end	9-Jun-2021

31st March 2025

Dear sir/madam,

The trial was an international multicentric study.

This trial was approved by the Spanish authorities but never started.

This study was not a Low Intervention Trial.

The active sites in Spain were:

1. HOSPITAL CLÍNIC DE BARCELONA: C/ Villarroel 170, 08036 Barcelona
2. HOSPITAL DEL MAR: Passeig Marítim, 25-29, 08003 Barcelona
3. HOSPITAL DE LA VALL D'HEBRON: Passeig de la Vall d'Hebron, 119-129, 08035 Barcelona

4. HOSPITAL UNIVERSITARI DE BELLVITGE: Carrer de la Feixa Llarga, s/n, 08907 L'Hospitalet de Llobregat, Barcelona
5. HOSPITAL DE LA SANTA CREU I SANT PAU DE BARCELONA: Carrer de Sant Quintí, 89, 08041 Barcelona
6. CONSORCI CORPORACIÓ SANITÀRIA PARC TAULÍ DE SABADELL: Parc Taulí, 1, 08208 Sabadell, Barcelona
7. HOSPITAL GERMAN TRIAS I PUJOL: Carretera de Canyet, s/n, 08916 Badalona, Barcelona
8. HOSPITAL VIRGEN DEL ROCÍO: Avenida Manuel Siurot, s/n, 41013 Sevilla
9. HOSPITAL SON ESPASES: Carretera de Valldemossa, 79, 07010 Palma, Illes Balears
10. HOSPITAL RIO HORTEGA: Calle Dulzaina, 4, 47012 Valladolid
11. HOSPITAL UNIVERSITARIO REY JUAN CARLOS: Avenida de la Constitución, 45, 28931 Móstoles, Madrid
12. HOSPITAL UNIVERSITARIO LUCUS AUGUSTI: Rúa Dr. Ulises Romero, s/n, 27003 Lugo
13. HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO: Travesía da Choupana, s/n, 15706 Santiago de Compostela, A Coruña
14. HOSPITAL UNIVERSITARIO SEVERO OCHOA: Avenida de Orellana, s/n, 28911 Leganés, Madrid

**Harmonised Protocol (SPAIN as a Member State):**

Protocol (version, date)	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
1.1, 09/04/2020	18-Apr-2020	16-Apr-2020	CEIm Hospital Clínic de Barcelona
2.0, 30/04/2020	12/05/2020	15-May-2020	CEIm Hospital Clínic de Barcelona
3.0, 10-Jul-2020	09/12/2020	02-Dec-2020	CEIm Hospital Clínic de Barcelona

**Declaration**

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS), hereby declares that the clinical trial with EudraCT Number 2020-001616-18, ended prematurely on 9<sup>th</sup> June 2021.

The study did not start due to a lack of recruitment given the improvement in the epidemiological situation of SARS-CoV-2.

Consequently, the sample size was not reached.

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

Yours faithfully,

Sara Campos  
Application Submitter CTU CLINIC