

**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	Cost-effectiveness of different antiretroviral treatment regimens in naïve patients. Randomized, open-label clinical trial comparing DRV/r+3TC, AUC+3TC (Kivexa)+RPV, or EVG/COBI/FTC/TDF (Stribild) for 48 weeks
Protocol code	Cost-Effect-Clinic
EudraCT Number	2014-004820-24
Product	<ul style="list-style-type: none"><li>• DRV/r+3TC (Darunavir potenciado con ritonavir + lamivudina),</li><li>• ABC+3TC (Kivexa)+ RPV (Abacavir + lamivudina + rilpivirina),</li><li>• ECG / COBI / FTC / TDF (Stribild) (Elvitegravir + cobicistat + emtricitabina + tenofovir disoproxil)</li></ul>
Sponsor	Fundació Clínic per a la Recerca Biomèdica
Trial end	July 11, 2017

28th July 2025

Dear sir/madam,

The trial was a single centre study conducted in Spain.

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

This study was not a Low Intervention Trial.

The active site was: Hospital Clínic de Barcelona, C/ Villarroel 170, 08036 (Barcelona)

Harmonised Protocol (version 1.0, 04/10/2014):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	02-June-2015	27-January-2015	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 2014-004820-24, ended prematurely on 11st July 2017.

The trial did not start due to the inability to recruit any eligible participants. As no patients were enrolled, the study was never initiated and no data were collected.

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

Yours faithfully,

Sara Campos  
Application Submitter CTU CLINIC