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Article Title:

Spanish HIV Researcher Faces €210,000 Fine Over Unauthorized Clinical Trial

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Hospital Carlos III

The Hospital Carlos III, where the study took place.

MADRID—A Spanish HIV/AIDS researcher is facing a hefty fine for violating clinical trial regulations. A court of appeals has upheld most of a lower court's verdict against Vicente Soriano, a physician at the Hospital Carlos III here and a well-known clinical researcher with hundreds of publications

to his name.

Soriano is liable for €210,000 for conducting a clinical trial without approval from the Spanish Agency for Medicines and Health Products, failing to obtain insurance for the trial, and informing participants he had his hospital's ethical approval when he did not, [according to the ruling](#) [1], which was published 14 January. But the court overturned a €6000 fine for obstructing the initial investigation, which took place in 2010.

The phase IV clinical trial, which Soriano [registered on ClinicalTrials.gov](#) [2] in July 2009, sought to establish whether HIV patients with undetectable levels of the virus in their blood can replace so-called protease inhibitors in their treatment cocktail with a powerful new compound, raltegravir, the first in a class called integrase inhibitors that has fewer side effects. Soriano's team divided patients into three groups with different treatment regimens; one group took raltegravir only once a day, instead of twice, the standard. (Simplifying a treatment regimen can help patients adhere to it.) The study enrolled 311 patients, 222 of whom completed 24 weeks of follow-up; a paper published in *HIV Clinical Trials* [3] in 2010 showed that raltegravir suppressed the virus successfully in all but 13 of them.

An anonymous tipster told Madrid's health department that the trial lacked the proper regulatory and ethical approvals, according to the court's ruling, and between 24 and 29 November 2010, the department sent inspectors to examine Soriano's records. In October 2011, a Madrid court issued him fines of €216,000.

Soriano appealed the fines on various points; the core of his defense, however, supported by three Spanish expert witnesses, was that the study was retrospective and observational, and that the treatment changes were within the normal realm of what doctors might recommend for any patient.

One of the seven magistrates hearing the case in Madrid's Superior Court of Justice agreed, but the majority did not. They wrote in [the verdict](#) [1] that "the appeal seeks to avoid the fact that the project not only proposed a change in dose but also a change in

the medicine." One of the expert witnesses seems to gloss over the fact that patients were put on a new type of drug by claiming, without evidence, that they were already taking raltegravir, the court added. The fines, two for "very serious" infractions and one for a "serious" infraction, were the lowest allowed by the law.

"This study was without doubt a clinical trial," that would need proper ethical approval, says bioethicist Ruth Macklin of Albert Einstein College of Medicine in New York City. After studying Soriano's study protocols, Macklin says they are incompatible with observational studies.

Soriano declined to be interviewed about the trial or the appeal, but in an e-mail to *ScienceInsider*, he said that he and his group are victims of "harassment" related to a plan to dismantle the infectious diseases group at Carlos III. The hospital is in the midst of a merger with Madrid's Hospital La Paz; both are owned by the Madrid regional government and parts were scheduled for privatization until this week, when a court ordered the cancellation of the plans.

It's unclear whether the hospital will take action against Soriano. While his appeal was pending, he continued his medical practice, but the ethics committee has not approved any clinical trials of his since March 2011, says Rafael Pérez-Santamarina Feijóo, the managing director of Hospital La Paz. Now that the court's final ruling is available, the hospital will evaluate how to proceed, Pérez-Santamarina says. A spokesperson for Madrid's Medical College [4] told *ScienceInsider* that it has taken no formal disciplinary action against Soriano.

Links:

[1] <http://ow.ly/t4fNc>

[2] <http://clinicaltrials.gov/ct2/show/study/NCT00941083?term=odis&rank=1>

[3] <http://www.ncbi.nlm.nih.gov/pubmed/20974575>

[4] <http://www.icomem.es/interior.aspx?lang=es-es&ld=88&p=1&o=1&eq=0>