



## No Point in Testing Controversial Stem Cell Treatment, Italian Panel Says

12-09-2013

An expert panel that the Italian government asked to come up with a trial design for a controversial Italian stem cell therapy has thrown in the towel. The group, made up of top Italian scientists, has concluded that the treatment—designed by the Stamina Foundation and the focus of an intense public debate in Italy—has no scientific foundation and that there is no point in doing the study, for which the Italian government has allocated €3 million.

The panel has sent its verdict to Italian Minister of Health Beatrice Lorenzin today, according to a ministry spokesperson; Lorenzin is now reviewing the report, which will be released tomorrow, the spokesperson says. But a source with inside knowledge of the deliberations told ScienceInsider earlier this week that the panel, in a meeting on 29 August, concluded that the Stamina method has no scientific merit. Italian news agency ANSA reported the same in a story published last night.

“The rationale on which the treatment is based was found to be both unclear and scientifically inconsistent,” according to the source, “while there was no evidence of efficacy in growing new neurons.”

Stamina's mesenchymal stem cell therapy has inflamed a passionate debate in Italy. Stem cell scientists say it lacks any scientific credibility, but patients and their supporters have demanded that the therapy be made available for a range of diseases for which Stamina claims benefit. In May, the Italian Parliament decided that the therapy should undergo a formal clinical trial; in July, Italy's new minister of health, Lorenzin, appointed a top-level scientific committee to review Stamina's clinical protocol and design the study.

The panel has concluded that Stamina President Davide Vannoni has not released records of any preclinical studies conducted by Stamina and “there is no data concerning the quality of the cellular preparation,” according to ScienceInsider's source. For instance, Stamina has been unable to show the presence of proteins that stem cells are expected to express when they form new neurons.

Elena Cattaneo, director of the UniStem stem cell center at the University of Milan—who last week was appointed an Italian senator for life—says she is not surprised. “This entire mess has been caused by a short circuit of politics,” she says, referring to the fact that Italian politicians decided on the trial as a way out of a political problem.

Reached by ScienceInsider on Wednesday, Vannoni said he had not yet heard about the rejection and said he's surprised the panel did not ask to see medical records of any of the patients already treated at the hospital in Brescia where the foundation operates. “They are doing very well,” he said.

Vannoni says that he presented those records in a judicial appeal against the appointment of the scientific panel, at the civilian court of the Lazio region. The panel's impartiality is in question, Vannoni says, because more than half of its members expressed a negative opinion on Stamina before the committee was

appointed. Several leading members of the panel declined to comment, including Fabrizio Oleari, president of the Italian National Institute of Health; Alessandro Nanni Costa, director of the National Transplant Centre; and Luca Pani, director of the Italian Medicines Agency (AIFA), which shut down Stamina's operation over a year ago.

Stamina provided the committee with a description of its methods on 1 August, but Lorenzin has not allowed members to share it with anyone, despite an open letter from the Italian stem cell community urging the protocol to be released for scientific scrutiny.

In 2012, stem cell scientist Massimo Dominici of the University of Modena and Reggio Emilia analyzed the composition of Vannoni's treatment at the request of AIFA and Italian magistrates investigating the foundation for alleged fraud. Dominici—who's president-elect of the International Society for Cellular Therapy—says that he found no evidence of newly grown neurons in Stamina's product, while stem cells were present only at "homeopathic doses." In July, a story in *Nature* claimed that Stamina's U.S. patent application was based on flawed data.

The committee's advice puts minister Lorenzin in a difficult position: She is under strong pressure from patients who want to undergo Stamina's therapy and are eager to have the trial proceed, while top scientists are telling her to abandon the idea. Complicating matters, the fraud investigation against the foundation—which is alleged to have treated patients with unapproved therapies in exchange for money—is ongoing.

Vannoni said on Wednesday that he was in Africa to negotiate a trial with government officials of a country he declined to identify. Two other countries—one in Europe and one in Asia—are interested in testing his method as well, he says. Another option would be to develop the therapy further at the Diabetes Research Institute in Hollywood, Florida, Vannoni says. Camillo Ricordi, the institute's scientific director, tells *ScienceInsider* that he has offered Vannoni to fast-track a study. "We find more and more evidence that real breakthroughs in medicine do not come only from traditional science, but also from nonprofessionals, people who try to cure patients with controversial strategies," Ricordi says.