



Italian Panel Meets With Controversial Stem Cell Provider to Discuss Trial

A panel of top science administrators and stem cell scientists met on Friday with Davide Vannoni, the president of an Italian foundation providing highly controversial stem cell treatments, in a first effort to hash out the details of a government-sponsored clinical trial of the therapy. But some Italian stem cell scientists remain squarely opposed to the study—and they're hopeful that recent news about alleged flaws in a patent application filed by Vannoni will help their case.

The stem cell treatments by Vannoni's Stamina Foundation have been hotly debated for many months. In May, the Italian Parliament decided that the treatment, based on cultured mesenchymal stem cells, can continue on a small scale; legislators also [ordered an 18-month clinical trial of the therapy and allocated €3 million to carry it out](#). But many stem cell scientists in Italy and abroad say it's too early for such a study because there is little to suggest that the therapy, whose details remain unpublished, might work. Massimo Dominici, president-elect of the International Society for Cellular Therapy, [has described the trial as "a waste of money."](#)

On 1 July, Italian Health Minister Beatrice Lorenzin appointed a scientific committee to coordinate the study, which includes the heads of the Superior Health Institute, the National Italian Transplant Centre, and the Italian Medicines Agency, along with Italian stem cell scientists. On the same day, Vannoni was supposed to provide the committee with protocols describing how his treatment works exactly. He failed to do so, because he's still working on their standardization. "Seven years of innovation cannot be standardized overnight," Vannoni tells *Science Insider*. As a result, the start of the trial has been delayed by at least a month.

On Friday, Vannoni met with the committee for the first time to discuss the protocols. No details of the talks were released after the meeting. Maria Chiara Carrozza, Italy's minister of universities and research, tells *Science Insider* that Stamina "must present the protocols as soon as possible. Anything else would be neither scientific nor ethical."

The committee has already indicated that cells used in the study must be produced following Good Manufacturing Practice, an international quality standard that Stamina has so far not adhered to. Vannoni says that he has his own conditions. Among these: There can be no changes to his protocol; the cells need to be produced at one facility, under the supervision of a Stamina biologist; and the trial must include patients with three different diseases. (Vannoni has suggested amyotrophic lateral sclerosis, cerebral palsy in infants, and a degenerative disease with non-neurological origin.)

If the committee doesn't accept his conditions, Vannoni says that he may move the research abroad. "We already have contacts abroad, even though we cannot reveal the potential location," says Gianfranco Merizzi, head of Medestea, a pharmaceutical and cosmetics company that signed a €2 million agreement to acquire the Stamina Foundation in 2012.

Confidence in the foundation seems to have suffered from [a story published by Nature on 2 July](#), which reported that two figures in a patent application by Stamina were lifted from papers published in scientific journals in 2003 and 2006. What's more, the picture from the 2003 paper shows cells cultured using a different protocol than described by Vannoni in the patent application. In the wake of the piece, Italian media—which had so far mostly given the Stamina Foundation the benefit of the doubt—have begun to take a much more critical look at the evidence underpinning the treatment.

Health Minister Lorenzin hasn't discussed the story directly, but said in a radio interview on 8 July that "patients must not consider the Stamina method a cure, because it is not." That's a far more cautious approach than that of her predecessor, Renato Balduzzi, who infuriated stem cell scientists last spring [by signing a decree that allowed Stamina's treatment to go forward](#).

Stem cell researcher Paolo Bianco of La Sapienza University in Rome says that *Nature's* revelations are another reason not to spend public money on the trial. "Our politicians should take their responsibility," he says.

But Vannoni says that he does not see the problem. "These figures are not part of a real publication, but only of a patent application," he tells *ScienceInsider*. Vannoni says that using the picture from the 2003 paper was okay because one of the authors, Elena Schegelskaya, worked for him to optimize the therapy protocols. "What is the fuss all about?" he asks. Italian media stories have reported that Schegelskaya did indeed work in Vannoni's lab between 2007 and 2009, but the picture dates from long before that time, when she worked at the Kharkov National Medical University in Ukraine.

Schegelskaya's name is also on a list of 13 people, including Vannoni, who have been under investigation since 2009 by a prosecutor in Turin for fraud, conspiracy, and allegedly administering drugs that could harm public health. The investigation is still continuing. It's unclear why Schegelskaya and Vannoni ended their collaboration in 2009.