

# Stem-cell fiasco must be stopped

**In the public interest, the Italian health minister should resolve the ongoing uncertainty over a government trial of a controversial therapy.**

“This is the end of the matter and we are very happy.” That was the reaction of Luca Pani, head of the Italian Medicines Agency, to the news in October that the Italian health minister had halted a government trial of a controversial stem-cell therapy. He is less happy now, and his dissatisfaction should be shared by anyone who cares about the rigorous use of scientific evidence and the protection of vulnerable patients.

Just when Pani and others in Italy were breathing a sigh of relief, an Italian court has thrown an unexpected spanner into the works. The court ruled last week that an expert committee behind a detailed report that demolished the scientific basis for the clinical trial of the claimed treatment was unlawfully biased (see *Nature* <http://doi.org/qgr; 2013>).

The judgement undermines the October decision made by health minister Beatrice Lorenzin to cancel the trial, which could yet be allowed to proceed. It must not. As *Nature* and independent experts have pointed out many times, there is no evidence that the claimed therapy works, and indeed it could be harmful.

Lorenzin should bring a stop to this uncertainty. She must release the members of the committee who prepared the critical report from a confidentiality agreement. They must be free to give the public their expert opinion on the claims of the commercial company Stamina, based in Brescia, which extracts stem cells from a patient’s bone marrow, manipulates them and then injects them back into the same patient’s blood or spinal cord. And Lorenzin should release to broader scrutiny the protocol that the company says it will follow to conduct the trial.

Already, members of one patient group have appealed for such openness, arguing that they have waited long enough to understand whether the Stamina method could help them live, and they want to be able to judge for themselves.

Lorenzin has responded that this is not in her power. It is unusual for a government-sponsored clinical trial to be so secretive, and it is natural that many are now asking questions about why the government insisted on confidentiality that would extend well beyond any trial, and why it should not be lifted when it is so clear that this would be in the public interest.

She must act now because things could soon get worse. Last week’s ruling by a regional administrative court in Rome said that a new committee should be appointed to take another look at the validity of the trial. To make this successor committee more balanced, the court suggested, it could invite foreign scientists to participate.

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This may seem a good idea, but it is venturing onto dangerous ground. There exist powerful international interests that support clinics offering unproven stem-cell therapies in countries such as Mexico and Uganda. Such countries lack the strict regulatory oversight that prevents the exploitation of desperate patients in Europe and the United States — and the clinics would love to see a regulatory loophole open in a European country. In setting up a replacement committee, Lorenzin must go to scientists who are independent of the companies that lobby for looser regulation of stem-cell therapies, and who work instead in internationally respected institutions.

Stamina had been treating seriously ill patients, mostly children, on a ‘compassionate basis’, since 2007 — until Pani’s agency closed its laboratory in Brescia in August 2012 for safety reasons. Some patient groups have lobbied passionately and publicly for access to the therapy that Stamina chief Davide Vannoni claims can cure a range of otherwise deadly diseases.

In November, when it seemed that the clinical trial was finally off the books, Vannoni led a demonstration in front of the parliamentary buildings in Rome, where patients threw their own blood at pictures of the president and prime minister. The emotion of those whose children are fatally ill is a powerful weapon.

The judgement — a ruling on an appeal by Stamina — shocked scientists in Italy and should shock scientists elsewhere. It seems not to take into account that the committee was restricted to considering Stamina’s clinical protocol and recommending which specific disorders should be treated in any clinical trial. The committee was asked only to assess whether the technical aspects of the proposed study satisfied ethical, clinical and legal standards.

The court argued that the committee lacked balance because most members were known opponents of the Stamina approach. It also complained that the committee had failed to look at documentation of Stamina’s claims to treatment successes (something beyond its mandate).

The uncertainty resulting from this latest judgement must be ended. Lorenzin must find the courage to act.