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Scientists explain about-face on MS trials

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Joanna Smith
Ottawa Bureau

OTTAWA—The scientists who advised the federal government to go ahead with clinical trials for a controversial new treatment for multiple sclerosis say it was new evidence — not public pressure — that changed their minds.

"The presence of advocacy groups certainly made me aware that there were a lot of people that want this procedure, but that did not pressure me. It did not influence me in any way, pro or con, to support the idea of doing the (small-scale clinical) trial," said Barry Rubin, a vascular surgeon at Toronto General Hospital.

The doctor is part of the expert working group tasked by the Conservative government and the Canadian Institutes of Health Research with monitoring \$2.4 million worth of diagnostic studies examining the theory of Italian researcher Dr. Paolo Zamboni.

Zamboni argues that multiple sclerosis is not an autoimmune disorder, as traditionally believed, but instead linked to narrowed veins, a condition he calls chronic cerebrospinal venous insufficiency (CCSVI).

In a surprise move, the working group decided at a closed meeting on Tuesday that there is enough evidence to begin clinical trials of the "liberation" treatment pioneered by Zamboni. The trials are at the Phase I and II levels, which generally involve a smaller number of people in order to evaluate the safety and efficacy of the proposed treatment before it is tested on a bigger group.

"It was not an easy decision," said Dr. Alain Beaudet, president of the Canadian Institutes of Health Research, who chaired the meeting in Toronto and said that after a majority of members supported the decision, everyone voted for it.

"We always want the scientific evidence to be stronger. The question is, when will it be strong enough to get going with this thing? There are people that will tell us it's too early. Others will tell us that it's too late. We're really trying here to do our best and balance science and patients, but it remains a human endeavour."

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Dr. Aaron Field, an associate professor of neuro-radiology at the University of Wisconsin, said a "key factor" in the decision was a meta-analysis of the research published so far, including a recent study by a Zamboni ally at the University of Buffalo that made headlines by suggesting CCSVI was a result, not a cause, of MS. The analysis took into account factors such as the number of subjects in research studies, and whether they used proper blinks and control groups.

"Even when you took a very conservative approach to that meta-analysis, it still came out looking like there was an association there (between CCSVI and MS)," said Field, who, like Beaudet and Rubin, stressed there is still not enough evidence to suggest cause and effect.

Beaudet, who had the working group sign confidentiality agreements that resulted in all but Field and Rubin declining to speak to the media, said he could not go into too much detail about the meta-analysis because its authors are submitting it for publication and he did not want to scoop them.

Field said he went into the meeting with an open mind but was still surprised by what he learned.

"I sort of thought that once somebody looked at all the studies, there would probably be nothing there. So once I saw that, that sort of reassured me that we're not all wasting our time and this really does need to be pursued," said Field, who added that if the seven ongoing diagnostic studies tip the balance the other way, he would advocate against continuing the trials.

Rubin said he remains unconvinced that CCSVI exists, and he is concerned about patients' safety. He confirmed that a third person has died as a result of the controversial treatment, but said he could not provide any details as the death is under investigation. The two previously reported deaths happened in California and Costa Rica.

Beaudet said he also did not expect to be advising Health Minister Leona Aglukkaq to proceed with funding clinical trials so quickly.

"That's what science is," said Beaudet. "If science always gave you the results you're expecting, I'm not sure it would be worth doing all that."

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