FDA issues warning on controversial MS treatment

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No reliable evidence supports use of 'liberation therapy,' agency says.

(HealthDay) -- Doctors and patients need to be aware of the potential risk of injuries and death associated with an experimental treatment for multiple sclerosis called liberation therapy, the U.S. Food and Drug Administration said in an alert issued Thursday.

Liberation therapy is used to treat chronic cerebrospinal venous insufficiency (CCSVI) -- a narrowing of veins in the neck and chest -- believed by some to cause multiple sclerosis (MS) or worsen the disease. They think it does so by impairing blood drainage from the brain and upper spinal cord.

The controversial procedure uses balloon angioplasty devices or stents to widen narrowed veins in the chest and neck. But the FDA has not

approved this treatment for chronic cerebrospinal venous insufficiency, and the agency said it has learned of deaths, strokes, damage to the treated vein, blood clots, cranial nerve damage, abdominal bleeding, and migration of stents in the body as a result of the treatment.

Also, studies examining a possible link between the two conditions are inconclusive, and the criteria used to diagnose chronic cerebrospinal venous insufficiency have not been adequately established, the FDA said.

"Because there is no reliable evidence from controlled clinical trials that this procedure is effective in treating MS, FDA encourages rigorously conducted, properly targeted research to evaluate the relationship between CCSVI and MS," Dr. William Maisel, chief scientist and deputy director for science in the FDA's Center for Devices and Radiological Health, said in an agency news release.

"Patients are encouraged to discuss the potential risks and benefits of this procedure with a neurologist or other physician who is familiar with MS and CCSVI, including the CCSVI procedures and their outcomes," he added.

One MS expert agreed with the FDA's warning, but said she understood why some patients might be drawn to the therapy.

"MS patients have a progressive disease. The response by many is to seek out the newest potential treatment or 'cure,'" said Dr. Karen Blitz-Shabbir, director of the Multiple Sclerosis Center at North Shore-LIJ Health System in Manhasset, N.Y. "Whether CCSVI will even be helpful is still unknown. MS centers around the country are *not* recommending this treatment at this time because it is unproven and may be dangerous," she added.

MS is a progressive autoimmune disease that affects the nervous system. Its underlying cause is unknown.

The FDA said that it is also is notifying doctors and clinical investigators who are planning or conducting clinical trials using medical devices to treat chronic cerebrospinal venous insufficiency that they must comply with FDA regulations for investigational devices.

Dr. Fred Lublin, director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at Mount Sinai School of Medicine in New York City, also welcomed the alert.

"The FDA's action is well-founded and provides an important safeguard for individuals with MS," he said.

"There are safety issues with the procedures associated with CCSVI, as detailed in the FDA alert," Lublin said. He also said the very existence of chronic cerebrospinal venous insufficiency is unclear. And, "whether there is any relationship between CCSVI and MS, as either a cause or consequence, is unproven," he added.

Without scientific studies supporting the treatment of chronic cerebrospinal venous insufficiency in patients with MS, the procedure cannot be recommended, Lublin said.

More information: The American Academy of Family Physicians has more about multiple sclerosis.