NIH studying progesterone to treat traumatic brain injuries

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By Rita Rubin, USA TODAY

Marc Baskett, 25, has recovered from a brain injury after receiving progesterone. He works with his parents, Jeff and Johnna, in Commerce, Ga.

Photos by Michael A. Schwarz, USA TODAY

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Males are one and one-half times more likely to sustain a traumatic brain injury than females. The leading causes:

A small study of progesterone in the treatment of traumatic brain-injured patients, including Baskett, was so promising the National Institutes of Health has financed a larger, nationwide study that is to start enrolling patients this week. Scientists are still trying to unravel how progesterone protects the brain, but laboratory and animal studies suggest that it is critical for normal development of brain cells and reduces swelling from trauma.

More than 1.5 million Americans sustain a traumatic brain injury each year. NIH is studying progesterone as a possible treatment option.
each year, and more than 50,000 of them die, according to the Centers for Disease Control and Prevention. In addition, more than 5 million survivors of such injuries have a long-term need for help with their daily activities, the CDC says.

Scientists have struggled to find a medication that improves survival and function in these patients. "Over 30 years, big pharma has sought drug after drug," says Arthur Kellerman, chairman of emergency medicine at Emory University in Atlanta. "Every single clinical trial of a treatment for brain injury has failed."

That is until the 100-patient pilot study of progesterone. The trial, designed mainly to test the hormone's safety, uncovered no serious side effects, Kellerman and his co-authors reported in 2007. Even more striking, the study found that patients given progesterone were 50% less likely to have died than those who received a placebo. And among moderate brain-injury survivors, those who received progesterone were less disabled. Some, like Baskett, made a full recovery.

Independent of the Emory researchers, but at around the same time, Chinese scientists conducted a similar trial with similar findings in 159 traumatic brain-injury patients.

But those studies weren't big enough to prove that progesterone effectively treats traumatic brain injury. "At this point, we have very high hopes, but hope is not the same as evidence," Kellerman says.

The NIH is betting at least $14 million, the cost of the first three years of the expanded trial, that progesterone will pan out, he says. The new trial plans to randomly assign a total of 1,140 newly brain-injured patients at 17 hospitals to either progesterone or a placebo, given intravenously for four days. Researchers will then assess patients' condition six months after treatment.

It will take about four years to enroll that many patients, says David Wright, associate professor of emergency medicine at Emory and the study's lead scientist. But Wright hopes the trial may have its answer before all 1,140 patients are enrolled.

An outside panel of experts, called a data safety monitoring board, will track progesterone's safety and effectiveness as the study proceeds (unlike the board, neither the researchers nor the patients will know who received progesterone and who the placebo until the study ends).

Typically, such boards recommend halting a study if one patient group clearly is doing better or worse than the other. If the board recommends stopping the trial early because it would be unethical to give a placebo instead of progesterone to any more patients, Wright says, "I would be the happiest person in the room."

For several years, Wright says, he has received daily e-mails from desperate parents and other family members: "We read about this. Is there anything that can be given to my son, my daughter?" He understands their pain, but he must tell them the treatment is experimental. Besides, Wright says, it's probably far too late for their children to benefit.

Tricking the brain

More than a quarter-century ago, physiological psychologist Donald Stein noticed that female rats recovered better from brain injuries that occurred when their natural progesterone levels were at their highest. He then tested whether giving progesterone to female rats injured at other points in their hormonal cycle and to male rats would improve recovery. The hormone worked in both cases.

"A lot of people thought this stuff was crazy," says Stein, a professor of emergency medicine at Emory. "I think the biggest downside to progesterone is its name. How could a female hormone work this way?"

Even doctors expressed reservations about using progesterone to treat men, he says. "Is it going to sterilize them? Is it going to make them gay?" they would ask, Stein says, although the hormone, which is present in men's brains as well as women's, doesn't affect secondary sex characteristics, such as facial hair or a deep voice.

In the pilot study, Kellerman says, families of male patients sometimes looked askance when he told them the experimental treatment was progesterone.

He'd explain that progesterone is very similar to testosterone, so administering it tricks the brain into thinking it's swimming in the male hormone. As a result, Kellerman would tell them, testosterone levels decline in men treated with progesterone, but they're back to normal within hours of turning off the IV.

It might be more accurate to call progesterone a "protection hormone" instead of a female hormone, Kellerman

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Source: CDC
By Frank Pompa, USA TODAY

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says. For example, Stein notes, when women with multiple sclerosis become pregnant and their progesterone levels rise, their MS symptoms improve markedly.

In the human trials, scientists use progesterone derived from yams. Stein isn't involved in the new trial, because he has a license with the company that makes progesterone, which he calls "dirt cheap."

The quicker the better

In the pilot trial, researchers lost precious time waiting for relatives to arrive and agree to enroll their unconscious loved ones.

This time, the scientists convinced their institutional review boards, which must approve human research, and the Food and Drug Administration to make a rare exception and allow immediate enrollment of eligible patients at any of the participating hospitals.

"The sooner you treat a brain injury," Stein says, "the better off you are."

In exchange, researchers were required to consult with local residents on how to publicize the trial. For example, Emory posted 10 billboards around Atlanta emblazoned with "Emergency brain injury research could save lives" and the trial's website. The scientists must still strive to contact relatives, who can withdraw their loved one from the study.

As soon as they got a call about their son's collision on a two-lane road in Lula, Ga., Baskett's parents sped from their Commerce home to Grady, about 65 miles away. A Life Flight helicopter had flown the young man to the hospital.

"We just wanted to get there to tell him goodbye," Johnna Baskett recalls.

His then-girlfriend had been driving. Other than a cut on her pinkie finger that required six stitches, she was unscathed, Baskett says, but the man in the other vehicle was killed and his wife severely injured.

When Baskett's parents arrived at Grady, they were ushered into a private room, where a doctor told them about their son's extensive injuries. Then a woman came in to ask if they would be interested in enrolling him in the progesterone trial.

Really, Baskett's mother says, it was an easy decision. Her son had "one foot in the grave and the other foot on a banana peel," she says. What did they have to lose by consenting to the trial?

When the study ended, they found out that their son did get progesterone, as they had suspected. Even so, he didn't simply wake up from the coma as though he had merely been asleep. His speech and short-term memory had been affected by damage to the frontal lobe of his brain. Even his laugh was different for awhile.

But, his mother says, by eight to 12 months after the accident, he finally got "back to Marc."

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