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<p>Caroline Connor's concerns about her son Mason's development began around his first birthday, when she noticed he wasn't talking or using any words. Their pediatrician didn't seem worried, but the speech delay persisted. At 2 and a half, Mason was diagnosed with autism.</p> <p>The Connors went on a mission, searching for anything that would help.</p> <p>"We just started researching on our own. And that's when my husband Joe came across Dr. Frye in a research study he was doing," Caroline said.</p> <p>Dr. Richard Frye, a pediatric neurologist, is one of many doctors searching for treatments that can help kids with autism. He's studying leucovorin, an inexpensive, generic drug derived from folic acid, also known as folate or vitamin B9. Leucovorin is currently prescribed to ease the side effects of cancer chemotherapy. Pregnant women are prescribed multivitamins with folic acid to prevent neural tube defects. The neural tube develops into the brain and spinal cord.</p> <p>Leucovorin isn't a cure for autism, but "it could really have a substantial impact on a very good percentage of children with autism," Frye said.</p>	« 179 words »	<p>Caroline Connor's concerns about her son Mason's development began around his first birthday, when she noticed he wasn't talking or using any words. Their pediatrician didn't seem worried, but the speech delay persisted. At 2 and a half, Mason was diagnosed with autism.</p> <p>The Connors went on a mission, searching for anything that would help.</p> <p>"We just started researching on our own. And that's when my husband Joe came across Dr. Frye in a research study he was doing," Caroline said.</p> <p>Dr. Richard Frye, a pediatric neurologist, is one of many doctors searching for treatments that can help kids with autism. He's studying leucovorin, an inexpensive, generic drug derived from folic acid, also known as folate or vitamin B9. Leucovorin is currently prescribed to ease the side effects of cancer chemotherapy. Pregnant women are prescribed multivitamins with folic acid to prevent neural tube defects. The neural tube develops into the brain and spinal cord.</p> <p>Leucovorin isn't a cure for autism, but "it could really have a substantial impact on a very good percentage of children with autism," Frye said.</p>
<p>This week, the Food and Drug Administration began the process of approving leucovorin as a treatment for autism, despite there having been no large, phase 3 clinical trials.</p> <p>"We do have some good preliminary evidence that leucovorin helps," Frye said. "But normally, the FDA would want to see at least a couple of large phase 3, placebo-controlled, randomized clinical trials. Right now, we only have phase 2B studies, and more research is needed to answer key questions, like how to dose it correctly, when to start and which children will benefit most."</p>		
<p>The theory behind the drug's use for autism postulates that some children have a blockage in the transport of folic acid into the brain that potentially contributes to some of the neurological problems associated with the disorder. Leucovorin bypasses that blockage and can help some autistic kids improve their ability to speak. Three randomized controlled trials of leucovorin to treat autism have shown positive effects on speech.</p>	« 67 words »	<p>The theory behind the drug's use for autism postulates that some children have a blockage in the transport of folic acid into the brain that potentially contributes to some of the neurological problems associated with the disorder. Leucovorin bypasses that blockage and can help some autistic kids improve their ability to speak. Three randomized controlled trials of leucovorin to treat autism have shown positive effects on speech.</p>
<p>Frye notes there are actually five blinded controlled studies to date, all positive, though at different doses and in different populations. Still, he says, "the evidence isn't yet where it would normally be for a drug."</p> <p>Frye said he was "disappointed" that his group had not received funding from the new NIH Autism Data Science Initiative and that he was not consulted on the design of upcoming leucovorin trials. "It's strange, because I've been leading this work for decades," he noted.</p>		<p>However, few currently prescribe leucovorin for autism.</p>
<p>The science of cerebral folate deficiency Cerebral folate deficiency (CFD), or a deficiency of folate in the brain, was first described by Dr. Vincent Ramaekers. Ramaekers found that some kids with neurodevelopmental disorders had normal levels of folic acid in the blood, but low levels in their spinal fluid. He then teamed up with Dr. Edward Quadros, who had been studying how an autoimmune disorder might lead to a blockage of folic acid transport into the brain. Ramaekers and Quadros found that autoantibodies against the folate receptor alpha (FRα), which transports folic acid from the blood into the brain and the placenta, might cause abnormal fetal brain development and some autism spectrum disorders.</p> <p>One study found that over 75% of children with autism spectrum disorder had FRα autoantibodies, as compared to 10-15% of healthy kids. There is evidence that there's a familial or genetic predisposition for developing FRα autoantibodies. While environmental and immune system dysregulation may also play a role, there's no evidence to suggest that vaccines cause the development of FRα autoantibodies.</p> <p>The brain has a backup system to the FRα known as the reduced folate carrier, or RFC. The RFC isn't as efficient a transporter as the FRα, but it can transport leucovorin, also known as folinic acid, into the brain. Enzymes in the brain convert leucovorin into the active form of folate.</p> <p>Treatment with leucovorin increases brain levels of folate in kids with CFD. In one study led by Frye, one-third of such kids experienced improvement in their speech and other behavior when treated with leucovorin. Two randomized trials conducted in France and India showed similar results. A folate receptor autoantibody test (FRAT) is available to help identify which children may most likely respond to leucovorin treatment.</p>	« 292 words »	<p>The science of cerebral folate deficiency Cerebral folate deficiency (CFD), or a deficiency of folate in the brain, was first described by Dr. Vincent Ramaekers. Ramaekers found that some kids with neurodevelopmental disorders had normal levels of folic acid in the blood, but low levels in their spinal fluid. He then teamed up with Dr. Edward Quadros, who had been studying how an autoimmune disorder might lead to a blockage of folic acid transport into the brain. Ramaekers and Quadros found that autoantibodies against the folate receptor alpha (FRα), which transports folic acid from the blood into the brain and the placenta, might cause abnormal fetal brain development and some autism spectrum disorders.</p> <p>One study found that over 75% of children with autism spectrum disorder had FRα autoantibodies, as compared to 10-15% of healthy kids. There is evidence that there's a familial or genetic predisposition for developing FRα autoantibodies. While environmental and immune system dysregulation may also play a role, there's no evidence to suggest that vaccines cause the development of FRα autoantibodies.</p> <p>The brain has a backup system to the FRα known as the reduced folate carrier, or RFC. The RFC isn't as efficient a transporter as the FRα, but it can transport leucovorin, also known as folinic acid, into the brain. Enzymes in the brain convert leucovorin into the active form of folate.</p> <p>Treatment with leucovorin increases brain levels of folate in kids with CFD. In one study led by Frye, one-third of such kids experienced improvement in their speech and other behavior when treated with leucovorin. Two randomized trials conducted in France and India showed similar results. A folate receptor autoantibody test (FRAT) is available to help identify which children may most likely respond to leucovorin treatment.</p>
<p>Frye's team has also identified new potential biomarkers, such as the soluble folate receptor protein, that could predict which children require higher doses.</p> <p>Frye notes that there are many nuances to treating CFD with leucovorin, including the addition of adjunctive treatments to optimize mitochondrial function.</p> <p>The side effects associated with leucovorin are mild. Some children experience hyperactivity during the first few weeks of treatment, but that typically subsides within a month or two. A similar pattern is seen with other B vitamins.</p> <p>Mason's "little bottle of hope" Mason Connor's first words came just three days after he started taking leucovorin at the age of 3, his parents say.</p> <p>Doctors can currently only prescribe the drug for autism off-label, which means repurposing a drug approved for one condition to treat another.</p> <p>"We've done the science, and the next step is that we want to get more funding so we can actually get it FDA approved," Frye said.</p>		
<p>He welcomed the FDA's recent interest but cautioned that it "may have been a little premature," given the gaps in knowledge and the need for physician education on how to prescribe leucovorin correctly in autism.</p>		<p>But</p>
<p>There's one big problem. "Leucovorin's an old drug and you can get it for a very low price. So nobody is going to make a lot of money on it. So there's no reason for them to invest," Frye said.</p>	« 40 words »	<p>there's one big problem.</p> <p>"Leucovorin's an old drug and you can get it for a very low price. So nobody is going to make a lot of money on it. So there's no reason for them to invest," Frye said.</p>
<p>Compounding the challenge: supply and quality vary. "Leucovorin is a generic, and different manufacturers use different additives," Frye explained. "Some formulations children with autism don't tolerate well."</p> <p>Frye used to recommend that patients use the generic form of leucovorin manufactured by West-Ward Pharmaceuticals, a U.S. subsidiary of Hikma, but, he says, "it ran out early this year. Right now, the only reliable source is through a high-quality compounding pharmacy that knows how to make it for kids with autism." Frye is in the process of establishing a for-profit company to manufacture the right form of leucovorin for kids with autism.</p>		<p>All of the studies on leucovorin to treat CFD and autism spectrum disorder have been relatively small. Although leucovorin is FDA-approved for other purposes, larger randomized, placebo-controlled clinical trials of leucovorin to treat autism spectrum disorders will be necessary to obtain specific FDA approval for that purpose.</p>
<p>An estimated 20-30% of all prescriptions in the U.S. are off-label, according to nonprofit Every Cure. This is often done as there are more than 14,000 known human diseases with no FDA-approved drugs to treat them. Drugs like leucovorin are frequently used off-label because doctors believe that the benefits outweigh the risks. However, there is often limited awareness about these treatments, so they may go unused.</p> <p>Dr. David Fajgenbaum says he's "literally alive today from a repurposed drug" after he was diagnosed with a rare cancer-like disease that almost killed him. His research into his disease led to a drug meant for another condition.</p> <p>"It's heartbreaking to think about drugs being on the pharmacy shelf while someone suffers from a disease," Fajgenbaum said.</p> <p>His nonprofit, Every Cure, uses AI to scour available medical data on diseases and treatments to uncover potential matches. Every Cure brought to light the work of Frye, Ramaekers, Quadros and others on leucovorin to treat autism.</p> <p>"I think our system is just flawed and there's this major gap where drug companies are great at developing new drugs for new diseases, and we as a system are really lousy at looking for new diseases for old drugs. That's why we started Every Cure — to unlock these hidden cures," Fajgenbaum said.</p> <p>Mason is now 5 years old, and the plan is for him to start mainstream kindergarten in the fall — helped toward a new path by an old medicine.</p>	« 248 words »	<p>An estimated 20-30% of all prescriptions in the U.S. are off-label, according to nonprofit Every Cure. This is often done as there are more than 14,000 known human diseases with no FDA-approved drugs to treat them. Drugs like leucovorin are frequently used off-label because doctors believe that the benefits outweigh the risks. However, there is often limited awareness about these treatments, so they may go unused.</p> <p>Dr. David Fajgenbaum says he's "literally alive today from a repurposed drug" after he was diagnosed with a rare cancer-like disease that almost killed him. His research into his disease led to a drug meant for another condition.</p> <p>"It's heartbreaking to think about drugs being on the pharmacy shelf while someone suffers from a disease," Fajgenbaum said.</p> <p>His nonprofit, Every Cure, uses AI to scour available medical data on diseases and treatments to uncover potential matches. Every Cure brought to light the work of Frye, Ramaekers, Quadros and others on leucovorin to treat autism.</p> <p>"I think our system is just flawed and there's this major gap where drug companies are great at developing new drugs for new diseases, and we as a system are really lousy at looking for new diseases for old drugs. That's why we started Every Cure — to unlock these hidden cures," Fajgenbaum said.</p> <p>Mason is now 5 years old, and the plan is for him to start mainstream kindergarten in the fall — helped toward a new path by an old medicine.</p>

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