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Health

New Stem Cell Drug Gives Baby Second Chance

By **Amanda Gardner**
HealthDay Reporter

FRIDAY, Oct. 14 (HealthDay News) -- Nelly Rojo could not believe her baby, Luis Fernando, was sick.

"He was too big, too strong, too beautiful," Rojo recalled of her first child, who was born at a robust 8.4 pounds.

But in the first 11 months of his short, frail life, Luis Fernando Rojo has endured more than most adults ever will: two cord blood transplants, three stem cell transfusions, an intubation and, just a few months ago, the verdict that he had only a 5 percent to 10 percent chance to live.

"I felt too bad, but I had a hope because I prayed to God every day," said Rojo, 22, speaking by phone in Luis's hospital room at University of Miami-Jackson Holtz Children's Hospital, where the boy has lived most of his life.

Apparent salvation ultimately came in the form of an experimental stem cell drug, given with special permission from the U.S. Food and Drug Administration. Luis's doctor predicts that the boy will go home for the first time within the next two weeks.

Luis was born with osteopetrosis, a rare and potentially fatal disorder that occurs when the body cannot produce enough osteoclasts, which are the cells that destroy bone tissue. As a result, too much bone is created, resulting in stunted growth, deformity, blindness and deafness.

The condition is curable with a bone marrow or cord blood transplant, if the donor is a match. Too often, however, a match can't be made.

"Because of the problem of rejection, we can cure less than 10 percent of kids because we can't get the match," said Dr. Steven Teitelbaum,

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the Messing professor of pathology at Washington University School of Medicine in St. Louis. Teitelbaum was a member of a team that first cured the disease in the 1980s. That bone marrow was obtained from an immunologically identical sibling, thereby avoiding the problem of rejection.

When a transplant is rejected, however, "we really don't have great medicines rather than routine immune suppression," said Luis's doctor, Dr. Gary Kleiner, a pediatric immunologist with the University of Miami School of Medicine.

Early in his life, Luis underwent two cord blood transplants from an unrelated donor: the first on Jan. 18, which his body rejected, and the second on April 19.

About a month after the second transplant, Luis developed a skin rash that worsened until, by early July, his whole body was red and covered with blisters. Then he started bleeding from the intestine. Luis had Graft-Versus-Host Disease (GVHD), a potentially deadly complication that affects about 30 percent of people receiving bone marrow or cord blood transplants.

Luis, however, did not respond to any of the conventional treatments, including high-dose steroids. Klein put his survival odds at 5 percent to 10 percent.

"I was too sad and scared because he can die," said Luis's mother, who has been sleeping in a recliner chair by her son's side since he was born. "He was crying a lot, and one week only cry and no stop, crying, crying."

There was, however, one option left.

Kleiner was teaming with Osiris, a Baltimore company, on a phase II trial of an investigational stem cell drug, Prochymal, for severe GVHD in adults. Prochymal is a formulation of a particular type of stem cell called mesenchymal stem cells.

"The child had failed all standard therapies, and we knew these cells were available. The company is doing phase II trials for severe adult GVHD," Kleiner explained. "We approached them to use it in the child as a last-resort effort."

Kleiner contacted Osiris on a Monday, the day after Luis started bleeding, then started the FDA paperwork. FDA permission to do emergency treatments is granted "fairly regularly," Kleiner said. In fact, approval came within a week and a half. Approval from the university's institutional review board took a little longer.

Nelly Rojo's prayers were starting to be answered.

"Within two weeks of receiving the cells, Luis's diarrhea had pretty much gone away, the rash dramatically improved and the GVHD came under control," Kleiner said.

But Luis was not safe yet.

When doctors started weaning Luis off his other medications, the GVHD returned. Luis received two more stem cell transfusions in August.

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"Since then, he's been very stable, although he does have somewhat of a skin rash," said Kleiner. Luis will still have to contend with long-term hearing and vision problems.

"He definitely won't be a normal child," Kleiner said. "He will need some early interventions, but there's no survival of osteopetrosis without a transplant and the GVHD would have killed him."

The procedure needs to be studied more intensively before it can be used routinely. But if those studies are successful, "this potentially would make the whole transplant process safer because it provides another opportunity to treat severe cases," Kleiner said.

Teitelbaum added: "This agent blocks a major complication of rejection of a transplant. If, in fact, it works, then this would hopefully permit the use of non-genetically identical stem cells in these transplants. It would be terrific."

More information

Visit the [Osteopetrosis](#) Web site for more on this disease.

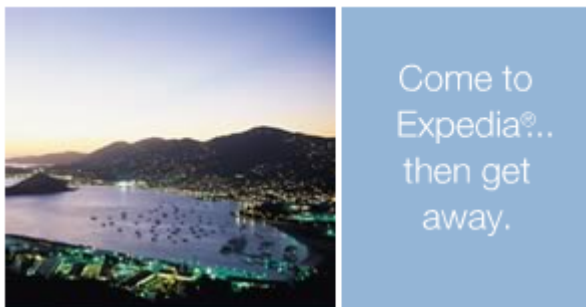
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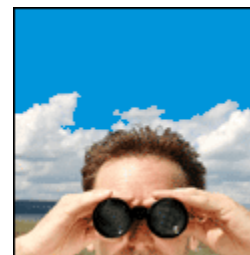
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