

Children at risk for type 1 diabetes show immune response when given oral insulin

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Credit: Robert Kraft/public domain

Children at risk for type 1 diabetes, who were given daily doses of oral insulin, developed a protective immune response to the disease that researchers with the Barbara Davis Center for Childhood Diabetes at the University of Colorado Anschutz Medical Campus say could possibly lay the groundwork for a vaccine against the chronic illness.

The pilot study, published Tuesday, April 21, in the *Journal of the American Medical Association (JAMA)*, was carried out in the U.S., Germany, Austria and the United Kingdom.

"This is the first time we have seen a healthful immune response from any therapy used in children who are at a high risk of [type 1 diabetes](#)," said Georgeanna Klingensmith, MD, professor of pediatrics at the University of Colorado School of Medicine at CU Anschutz, who led the U.S. side of the research. "The results showed that it was safe and none of the children developed [diabetes](#), insulin antibodies or hypoglycemia."

Klingensmith said children receiving the highest dose of oral insulin showed the greatest immune response.

Type I diabetes is a chronic, life-threatening disease causing up to 200 deaths each year nationwide. Children who have the disease must inject insulin several times a day for the rest of their lives because their own immune system has killed the cells in their pancreas that create insulin.

In this study, children who had a strong family history of type 1 diabetes were given oral insulin or a placebo once a day for three to 18 months to determine if the insulin could provoke an immune response without side-effects. The children were between two and seven years old.

Only two out of 10 children treated with a placebo showed any immune response.

But among those receiving oral insulin, the immunity increased with the dosage.

- 16.7 percent of children who received 2.5 mg of insulin a day saw an immune response.
- 33 percent of children who received 7.5 mg of insulin showed an

immune response.

- 83.3 percent of children taking 67.5 mg of insulin a day demonstrated an [immune response](#).

"The results show that the oral insulin was safe," Klingensmith said.

"They also tell us that we need to do a larger trial with more [children](#) to see if these findings hold up."

While Klingensmith is reluctant to read too much into the findings, she said under a best case scenario, they could lead to the development of a vaccine for type 1 diabetes.

"That is the ultimate goal," she said.

More information: *JAMA*, doi:10.1001/jama.2015.2928
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