

2 drugs better than 1 to treat youth with type 2 diabetes

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A combination of two diabetes drugs, metformin and rosiglitazone, was more effective in treating youth with recent-onset type 2 diabetes than metformin alone, a study funded by the National Institutes of Health (NIH) has found. Adding an intensive lifestyle intervention to metformin provided no more benefit than metformin therapy alone.

The study also found that metformin therapy alone was not an effective treatment for many of these youth. In fact, metformin had a much higher failure rate in study participants than has been reported in studies of adults treated with metformin alone.

The Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study is the first major comparative effectiveness trial for the treatment of type 2 diabetes in [young people](#). TODAY was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of NIH. Study results will appear in the [New England Journal of Medicine](#).

"The results of this study tell us it might be good to start with a more aggressive drug treatment approach in youth with type 2 diabetes," said Philip Zeitler, M.D., Ph.D., the TODAY study chair and a pediatric endocrinologist at Children's Hospital Colorado, Aurora. "We are learning that type 2 diabetes is a more aggressive disease in youth than in adults and progresses more rapidly, which could be why metformin alone had a higher than expected failure rate."

The TODAY study tested how well and for how long each of three treatment approaches controlled [blood glucose levels](#) in youth enrolled from ages 10 to 17 with type 2 diabetes. Participants were randomly assigned to one of three treatment groups: metformin alone, metformin and rosiglitazone together, and metformin plus intensive lifestyle changes aimed at helping participants lose weight and increase physical activity.

The study found that treatment with metformin alone was inadequate for maintaining acceptable, long-term, blood glucose control in 51.7 percent of youth over an average follow-up of 46 months. The failure rate was 38.6 percent in the metformin and rosiglitazone group, a 25.3 percent reduction from metformin alone. In the metformin plus lifestyle group the failure rate was 46.6 percent.

The childhood obesity epidemic has led to the emergence of type 2 diabetes in youth. However, because type 2 diabetes has been primarily an adult illness, information about how to effectively treat youth is limited, and pediatric diabetes experts have had to rely on what is known about adult treatment.

Currently, metformin is the standard treatment for young people with type 2 diabetes and the only oral drug approved for this use by the U.S. Food and Drug Administration.

The longer a person has type 2 diabetes, the greater the likelihood of developing complications including coronary artery disease, stroke, kidney and eye disease, and nerve damage, making it critical for young people with type 2 diabetes to quickly achieve and sustain control of their blood glucose.

"This important study provides much-needed information about how to treat type 2 diabetes in young people. Earlier studies in adults have

shown that early, effective treatment can prevent serious and costly diabetes complications later in life," said NIDDK Director Griffin P. Rodgers, M.D. "Longer-term follow up will be important to understand whether more aggressive therapy for youth with type 2 diabetes will yield long-term benefits as they move into adulthood."

In September 2010, the FDA restricted the use of rosiglitazone because of studies linking the medicine to a higher risk of heart attacks and stroke in adults. The TODAY Data Safety and Monitoring Board-an independent group of health and science experts-carefully examined all safety data for TODAY participants and recommended that the study should continue to test rosiglitazone. Rosiglitazone is sold commercially as Avandia.

Studies have shown lifestyle-change programs to be effective in improving blood glucose control for adults with type 2 diabetes. However, the TODAY lifestyle intervention-a family-based weight-management program that included intensive education and activities delivered one-on-one by trained study staff-added no benefit to the metformin therapy. Some youth lost weight during the study, but the majority did not.

"Despite a rigorous [lifestyle intervention](#), we were unable to achieve sustained lifestyle changes in these youth, though similar strategies have proven effective in adults," said Barbara Linder, M.D., Ph.D., NIDDK senior advisor for childhood [diabetes](#) research. "TODAY investigators will look more closely at those youth who succeeded in losing weight to better understand how to achieve effective lifestyle change in this population."

The study enrolled 699 youth who had [type 2 diabetes](#) for less than two years and a body mass index (BMI) at the 85th percentile or greater. BMI is a measurement of weight in relation to height. Overweight

children have a BMI at the 85th to 94th percentile for their age and sex, while obesity is defined as a BMI at the 95th percentile or more. The TODAY participants had an average BMI at the 98th percentile.

Provided by National Institute of Diabetes and Digestive and Kidney Diseases

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