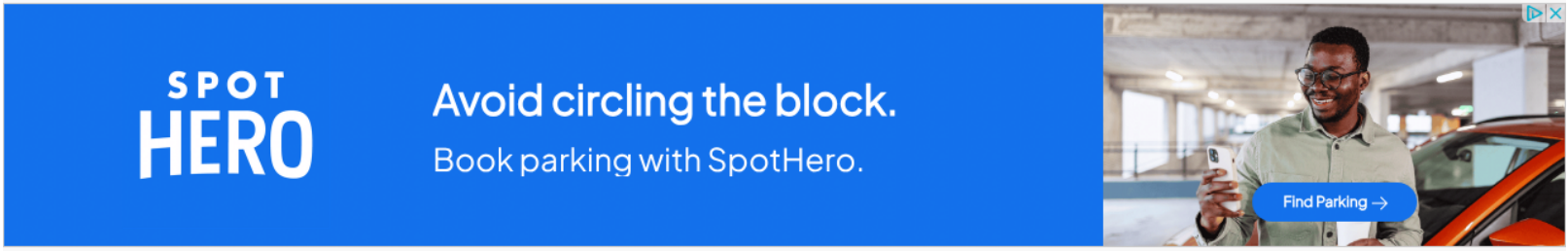
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Patients Taking Experimental Obesity Drug Lost More Than 50 Pounds, Maker Claims

The data have not yet been peer reviewed or published. But experts said the drug may give people with obesity an alternative to bariatric surgery.

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Eli Lilly's drug, tirzepatide, if approved, could cost more than $1,500 a month if the price turns out to be like that of a similar drug made by Novo Nordisk. Mike Segar/Reuters



By Gina Kolata

Published April 28, 2022 Updated May 1, 2022

An experimental drug has enabled people with obesity or who are overweight to lose about 22.5 percent of their body weight, about 52 pounds on average, in a large trial, the drug's maker announced on Thursday.

The company, Eli Lilly, has not yet submitted the data for publication in a peer-reviewed medical journal or presented them in a public setting. But the claims nonetheless amazed medical

Eli Lilly & Co.
Exhibit 2025
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on Thursday.

The company, Eli Lilly, has not yet submitted the data for publication in a peer-reviewed medical journal or presented them in a public setting. But the claims nonetheless amazed medical experts.

"Wow (and a double Wow!)" Dr. Sekar Kathiresan, chief executive of Verve Therapeutics, a company focusing on heart disease drugs, wrote in a tweet. Drugs like Eli Lilly's, he added, are "truly going to revolutionize the treatment of obesity!!!"

Dr. Kathiresan has no ties to Eli Lilly or to the drug.

Dr. Lee Kaplan, an obesity expert at the Massachusetts General Hospital, said that the drug's effect "appears to be significantly better than any other anti-obesity medication that is currently available in the U.S." The results, he added, are "very impressive."

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Dr. Kaplan who consults for a dozen pharmaceutical companies, including Eli Lilly, said he was not involved in the new trial or in the development of this drug.

On average, participants in the study weighed 231 pounds at the outset and had a body mass index, or B.M.I. — a commonly used measure of obesity — of 38. (Obesity is defined as a B.M.I. of 30 and higher.)

Editors' Picks

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At the end of the study, those taking the higher doses of the Eli Lilly drug, called tirzepatide, weighed about 180 pounds and had a B.M.I. just below 30, on average. The results far exceed those usually seen in trials of weight-loss medications and are usually seen only in surgical patients.

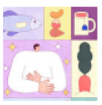
Some trial participants lost enough weight to fall into the normal range, said Dr. Louis J. Aronne, director of the comprehensive weight control center at Weill Cornell Medicine, who worked with Eli Lilly as the study's principal investigator.

Most of the people in the trial did not qualify for bariatric surgery, which is reserved for people with a B.M.I. over 40, or those with a B.M.I. from 35 to 40 with sleep apnea or Type 2 diabetes. The risk of developing diabetes is many times higher for people with obesity than for people without it.

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An Eli Lilly spokeswoman said the company did not have a public timeline for seeking approval of the drug with the Food and Drug Administration.

Because obesity is a chronic medical condition, patients would need to take tirzepatide for a lifetime, as they do for blood pressure or cholesterol drugs, for example.

Dr. Robert F. Kushner, an obesity expert at Northwestern University's Feinberg School of Medicine and a paid consultant to Novo Nordisk, said the new drug along with a similar but less effective one by Novo Nordisk, can close a so-called treatment gap.

Diet and exercise, combined with earlier obesity drugs, usually yield perhaps a 10 percent weight loss in patients. That is enough to improve health, but not nearly enough to make a big difference in the lives of peoples who are obese.

The only other treatment is bariatric surgery, which can result in

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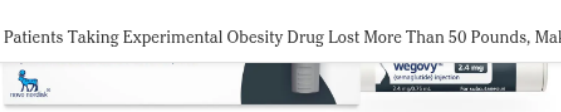
The only other treatment is bariatric surgery, which can result in substantial weight loss. But many people are ineligible or simply do not want the surgery.

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With the Eli Lilly drug and Novo Nordisk's semaglutide, which was recently approved, "we really are on the cusp of a new way of treatment," Dr. Kushner said.





Semaglutide, marketed as Wegovy, Novo Nordisk's own treatment for diabetes and weight loss. Cristian Mihaila/Novo Nordisk, via Associated Press

But prices may be a barrier. Insurers often will not pay for weight loss drugs. The Novo Nordisk drug, whose brand name is Wegovy, has a list price of $1,349.02 per month.

Experts worry that tirzepatide, if approved, might carry a price in the same range. Many people who could most benefit from weight loss may be unable to afford such expensive drugs.

The Eli Lilly study lasted 72 weeks and involved 2,539 participants. Many qualified as obese, while others were overweight but also had such risk factors as high blood pressure, high cholesterol levels, cardiovascular disease or obstructive sleep apnea.

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They were divided into four groups. All received diet counseling to reduce their calorie intake by about 500 a day.

One group was randomly assigned to take a placebo, while the other three received doses of tirzepatide ranging from 5 milligrams to 15 milligrams. Patients injected themselves with the drug once a week.

Those taking the highest dose lost the most weight, the investigators found. Participants taking a placebo lost 2.4 percent of their weight, an average of 5 pounds, typical for a diet study.

Dr. Nadia Ahmad, senior medical director of Eli Lilly's obesity program, said that seeing the results was an emotional moment for her.

"I don't think I ever imagined we could reach this degree of weight loss with a medicine," she said. "We only got this far with surgery."

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For decades, people who are overweight or have obesity were told that solving the problem was up to them. Diet and exercise were the prescriptions, and they simply did not work for many people. Most tried diet after diet, only to regain any weight they lost.

Last year, the situation began to change when Novo Nordisk received approval from the Food and Drug Administration to market semaglutide. The drug can elicit a 15 percent to 17 percent weight loss in people with obesity.

The medications are among a new class of drugs called incretins, which are naturally occurring hormones that slow stomach emptying, regulate insulin and decrease appetite. The side effects include nausea, vomiting and diarrhea. But most patients tolerate or are not bothered by these effects.

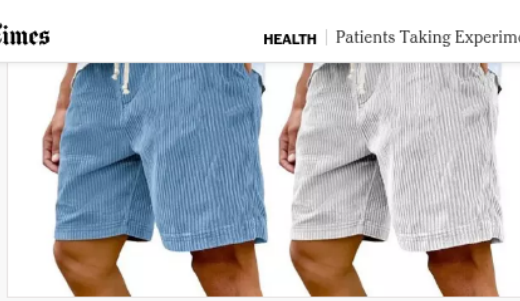
Incretins raise the bar for the sort of weight loss possible with drugs. But they also pose difficult questions about whether bariatric surgery is becoming a relic of the past. Already there are new versions of incretins in development that might be even more powerful than the Eli Lilly drug.

Even without them, Dr. Aronne said, the reductions observed with the Eli Lilly drug are “squarely in the range of surgical weight loss.”

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Some patients who have had bariatric surgery describe mixed results. Sarah Bramblette, a board member of the Obesity Action Coalition, had bariatric surgery only to regain the weight.

Now 44, she weighed 500 pounds when she had the operation 20 years ago, which enabled her to get down to 250 pounds. Over the years, though, her weight crept back up to 490 pounds. She needed heart surgery but was too heavy for the operating table. Diets — and she has tried them repeatedly — did not help.

Novo Nordisk's semaglutide enabled her to get down to 430 pounds. Now, Ms. Bramblette said, she would like to try the Eli Lilly drug if it becomes available.

"Trust me, I would not choose to be this size," Ms. Bramblette said. "I need to lose weight."

Weight Loss


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A version of this article appears in print on April 29, 2022, Section A, Page 16 of the New York edition with the headline: Experimental Obesity Drug Produces 20% Weight Loss. Order Reprints | Today's Paper | Subscribe

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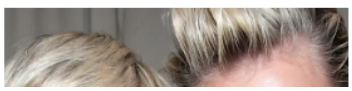


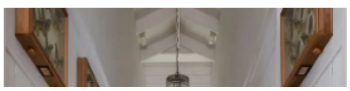
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