

Inhaled Insulin with or Instead of Oral Medications for Type 2 Diabetes

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The full report is titled "Inhaled Insulin Improves Glycemic Control When Substituted for or Added to Oral Combination Therapy in Type 2 Diabetes. A Randomized, Controlled Trial." It is in the 18 October 2005 issue of *Annals of Internal Medicine* (volume 143, pages 549-558).

The authors are J. Rosenstock, B. Zinman, L.J. Murphy, S.C. Clement, P. Moore, C.K. Bowering, R. Hendler, S.-P. Lan, and W.T. Cefalu.

What is the problem and what is known about it so far?

Type 2 diabetes mellitus (adult-onset diabetes) interferes with the body's ability to store energy from food, resulting in high blood sugar levels that can lead to problems, such as kidney failure, blindness, and heart disease. Insulin helps the body to convert food to stored energy and keeps blood sugar levels within the normal range. In type 2 diabetes, body tissues are resistant to the effects of insulin and patients lack effective insulin levels that are required to keep their blood sugar levels normal. Some patients can overcome the abnormalities by taking prescription pills, while others must take insulin injections at least once daily. Researchers have been exploring ways to give insulin to diabetic patients other than by injection. One alternative is inhaled insulin, whereby patients breathe insulin into their lungs by using a special device.

Why did the researchers do this particular study?

To find out whether inhaled insulin improves the control of type 2 diabetes in patients who do not achieve good control with pills alone.

Who was studied?

309 patients with type 2 diabetes who were taking pills and had poorly controlled diabetes. The researchers defined poor control as a hemoglobin A_{1c} level between 8% and 11%. Hemoglobin A_{1c} levels indicate blood sugar levels over the past 3 months. An important goal of diabetes treatment is to lower hemoglobin A_{1c} levels to 7% or less.

How was the study done?

The researchers assigned patients at random to continue taking the diabetes pills, to add inhaled insulin before meals to the pills, or to stop taking the pills and take only inhaled insulin before meals. Study patients adjusted inhaled insulin doses according to blood sugar levels. After 12 weeks, the researchers compared the changes in hemoglobin A_{1c} levels in the 3 groups. They also examined side effects, including weight gain, and episodes during which blood sugar levels were too low.

What did the researchers find?

Improvements in hemoglobin A_{1c} level were best in the group that took inhaled insulin with the pills, second-best in the group that took only inhaled insulin, and worst in the group that took only pills. Mild weight gain, episodes of low blood sugar levels, and mild cough were more frequent in the inhaled insulin groups. Lung function was similar in all groups.

What were the limitations of the study?

The authors did not compare inhaled insulin with injected insulin. In addition, whether patients would continue to show improved blood sugar levels or have side effects if they used inhaled insulin for longer than 12 weeks is not known. Of note, the inhaler device is currently large and allows dosing of 2.5 to 3.0 units of insulin. Injected insulin currently allows for finer adjustments in dose than inhaled insulin.

What are the implications of the study?

Inhaled insulin may be a treatment option for type 2 diabetes when patients do not achieve good control by using pills alone.

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