

## Nocturnal glucose control with an artificial pancreas at a diabetes camp.

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#### Abstract

##### **BACKGROUND:**

Recent studies have shown that an artificial-pancreas system can improve glucose control and reduce nocturnal hypoglycemia. However, it is not known whether such results can be replicated in settings outside the hospital.

##### **METHODS:**

In this multicenter, multinational, randomized, crossover trial, we assessed the short-term safety and efficacy of an artificial pancreas system for control of nocturnal glucose levels in patients (10 to 18 years of age) with type 1 diabetes at a diabetes camp. In two consecutive overnight sessions, we randomly assigned 56 patients to receive treatment with an artificial pancreas on the first night and a sensor-augmented insulin pump (control) on the second night or to the reverse order of therapies on the first and second nights. Thus, all the patients received each treatment in a randomly assigned order. The primary end points were the number of hypoglycemic events (defined as a sensor glucose value of <63 mg per deciliter [3.5 mmol per liter] for at least 10 consecutive minutes), the time spent with glucose levels below 60 mg per deciliter (3.3 mmol per liter), and the mean overnight glucose level for individual patients.

##### **RESULTS:**

On nights when the artificial pancreas was used, versus nights when the sensor-augmented insulin pump was used, there were significantly fewer episodes of nighttime glucose levels below 63 mg per deciliter (7 vs. 22) and significantly shorter periods when glucose levels were below 60 mg per deciliter ( $P=0.003$  and  $P=0.02$ , respectively, after adjustment for multiplicity). Median values for the individual mean overnight glucose levels were 126.4 mg per deciliter (interquartile range, 115.7 to 139.1 [7.0 mmol per liter; interquartile range, 6.4 to 7.7]) with the artificial pancreas and 140.4 mg per deciliter (interquartile range, 105.7 to 167.4 [7.8 mmol per liter; interquartile range, 5.9 to 9.3]) with the sensor-augmented pump. No serious adverse events were reported.

##### **CONCLUSIONS:**

Patients at a diabetes camp who were treated with an artificial-pancreas system had less nocturnal hypoglycemia and tighter glucose control than when they were treated with a sensor-augmented insulin pump. (Funded by Sanofi and others; ClinicalTrials.gov number, NCT01238406.)