

Hybrid closed-loop technology improves maternal glucose levels for pregnant women with type 1 diabetes: Clinical trial

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For pregnant women with type 1 diabetes, a technology giving insulin doses, as informed by a smartphone algorithm, helps them better manage

their blood sugars compared with traditional insulin pumps or multiple daily injections, according to a new randomized trial published in *The New England Journal of Medicine (NEJM)* and presented at the European Association for the Study of Diabetes (EASD) meeting in Hamburg (2–6 October).

Despite better systems for monitoring blood sugars and delivering insulin, hormonal changes and altered eating patterns during [pregnancy](#) mean that most women struggle to reach the recommended blood sugar targets. This means that complications related to having type 1 [diabetes](#) during pregnancy are widespread, affecting one in every two newborn babies.

For the baby, these include [premature birth](#), need for intensive care after birth, and being too large at birth, which increases the lifelong risk of overweight and obesity. Low blood sugars, excess weight gain, and [high blood pressure](#) during pregnancy are common among mothers.

The authors of the study say that, as a result of these findings, this type of technology should now be offered to all pregnant women with type 1 diabetes to help improve maternal blood sugars.

In the study, researchers trialed a technology known as hybrid closed-loop or artificial pancreas. The technology consists of an algorithm which sits on a smartphone and communicates with the current continuous glucose monitoring and insulin pump systems. The system adjusts insulin doses every 10–12 minutes according to [blood sugar levels](#), meaning that it continuously responds to the persistent changes in blood sugar levels throughout pregnancy.

They compared this technology with the current continuous glucose monitoring and insulin systems, where women supported by specialist diabetes maternity teams, make multiple daily decisions about insulin

doses.

The study involved 124 pregnant women with type 1 diabetes aged 18–45 years who managed their condition with daily insulin therapy. Half were randomly allocated to use the hybrid closed-loop technology, and half to use the traditional insulin therapy (insulin pumps or multiple daily injection methods).

They took part for approximately 24 weeks (from 10–12 weeks) until the end of pregnancy. The study took place in nine NHS hospitals in England, Scotland, and Northern Ireland.

On average, pregnant women used the hybrid closed-loop technology for more than 95% of the time. Using the technology helped to substantially reduce maternal blood sugars throughout pregnancy.

Compared to traditional insulin therapy methods, women who used the technology spent more time in the target range for pregnancy blood sugar levels (68% vs. 56%—equivalent to an additional 2.5–3.0 hours every day throughout pregnancy). It was safely initiated during the first trimester, which is a crucially important time for babies' development.

The blood sugar levels improved consistently in mothers across all ages and regardless of their previous blood sugar levels or previous insulin therapy. These improvements were achieved without additional low blood glucose events and without additional [insulin](#). Women using the technology also gained 3.5 kg (equal to 7.7 lbs) less weight and were less likely to have blood pressure complications during pregnancy.

Importantly, women using the technology also had fewer antenatal clinic appointments and fewer out-of-hours calls with maternity clinic teams, suggesting that this technology could also be time saving for pregnant women and for stretched maternity services.

"For a long time, there has been limited progress in improving blood sugars for women with type 1 diabetes, so we're really excited that our study offers a new option to help [pregnant women](#) manage their diabetes," says lead author, Professor Helen Murphy (University of East Anglia, Norwich, UK).

"We know that for women with type 1 diabetes, unborn babies are exquisitely sensitive to small rises in blood sugars, so keeping blood sugar levels within the normal range during pregnancy is crucial to reduce risks for the mother and child."

"Previous studies have confirmed that every extra hour spent in the blood sugar target range reduces the risks of premature birth, being too large at birth and need for admission to neonatal intensive care unit. This technology is game changing, in that it will allow more [women](#) to have safer, healthier, more enjoyable pregnancies, with potential for lifelong benefits for their babies."

The researchers note some limitations, including that the current study was too small for a detailed examination of baby health outcomes, and that their results are specific to the [CamAPS FX technology](#), so cannot be extrapolated to closed-loop systems, with higher blood sugar targets, that may not be applicable for use during pregnancy.

More information: Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMoa2303911](https://doi.org/10.1056/NEJMoa2303911).
www.nejm.org/doi/full/10.1056/NEJMoa2303911

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