

Research offers pregnant women new hope for safe and effective gestational diabetes treatment

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Researchers have taken a significant step forward in the management of gestational diabetes mellitus after a clinical trial involving pregnant



women provided new hope for expectant mothers suffering the condition.

The study by academics at University of Galway offers new hope for safe and effective treatment for <u>pregnant women</u> suffering from the condition and alleviates concerns over the drug <u>metformin</u>, with the trial showing no difference in outcomes for mothers and their newborns.

The findings from the trial are published in the *Journal of the American Medical Association (JAMA)*.

Gestational diabetes is a global health issue affecting almost 3 million pregnant women worldwide every year. It is a condition characterized by elevated <u>blood sugar levels</u> during pregnancy, posing increased <u>health</u> <u>risks</u> for both mothers and their babies.

Professor Fidelma Dunne, Professor of Medicine at University of Galway and Consultant Endocrinologist at Saolta University Health Care Group, managed the EMERGE, randomized, placebo-controlled trial, involving more than 500 pregnant women.

It found:

- Women assigned to metformin were 25% less likely to need insulin, and when insulin was necessary, it was started later in the pregnancy. Metformin is used routinely in the treatment of type 2 Diabetes and has been widely available for over 60 years.
- Fasting and post-meal sugar values in the mother were significantly lower in the metformin exposed group at weeks 32 and 38.
- Women receiving metformin gained less weight throughout the trial and maintained this weight difference at the 12-week post-delivery visit.



- Importantly, delivery occurred at the same mean gestational age (39.1 weeks) in both groups. There was no evidence of any increase in preterm birth (defined as birth before 37 weeks) among those who received metformin.
- Infants born to mothers who received metformin weighed, on average, 113g less at birth, with significantly fewer infants classified as large at birth, or weighing over 4kg (8lbs 8ounces).
- While there was a slight reduction in infant length (0.7cm), there were no other significant differences in baby measurements.
- There were slightly more babies who were small at birth but this did not reach statistical significance.

The study also revealed no differences in adverse neonatal outcomes, including the need for intensive care treatment for new-borns, respiratory support, jaundice, congenital anomalies, birth injuries or low sugar levels.

Additionally there were no variations in rates of labor induction, cesarean delivery, maternal hemorrhage, infection or blood pressure issues during or after birth.

Dunne presented the results at the <u>59th Annual Meeting of the European Association for the Study of Diabetes</u> in Hamburg, Germany.

Dunne said, "While there is convincing evidence that improved sugar control is associated with improved pregnancy outcomes, there was uncertainty about the optimal management approach following a diagnosis of gestational diabetes."

"In our pursuit of a safe and effective treatment option we explored an alternative approach—administering the drug metformin. A previous trial compared metformin to insulin and found it to be effective, yet concerns remained, especially regarding <u>preterm birth</u> and infant size."



To address concerns comprehensively, the team at University of Galway conducted a ground-breaking placebo-controlled-trial, filling a critical gap in the gestational diabetes treatment landscape.

- 535 pregnant women took part, with 268 receiving metformin and 267 a placebo.
- 98% of women remained in the trial until delivery, with 88% completing the 12-week post-delivery follow up assessment.
- Only 4.9% of women discontinued medication due to side effects, highlighting the safety of the interventions.

Dunne said, "Traditionally, gestational diabetes has been managed initially through dietary advice and exercise, with insulin introduced if sugar levels remain sub-optimal. While effective in reducing poor pregnancy outcomes, insulin use is associated with challenges, including low sugars in both the mother and infant which may require neonatal intensive care, excess weight gain for mothers, and higher cesarean birth rates."

"For mothers with gestational diabetes, they are also at greater risk of high blood pressure and preeclampsia."

"Babies born to mothers with gestational diabetes face their own set of risks, such as excessive weight at birth, birth injuries, respiratory difficulties and low sugar levels after delivery potentially requiring admission to neonatal intensive care. Gestational diabetes also increases the lifetime risk of diabetes for these mothers and their children. In addition mothers have an elevated lifetime risk of cardiovascular disease. Furthermore, low and middle-income countries bear a significant burden of gestational diabetes cases."

Dunne added, "The results from the EMERGE study are a significant step forward for women with gestational <u>diabetes</u>. Metformin has



emerged as an effective alternative for managing <u>gestational diabetes</u>, offering new hope for <u>expectant mothers</u> and health care providers worldwide."

More information: Dunne et al, *JAMA* (2023). doi.org/10.1001/jama.2023.19869

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