

# DECIDE: A Comparative Effectiveness Trial of Metformin Versus Insulin for the Treatment of Gestational Diabetes

NCT06445946

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Status	RECRUITING
Phase	Phase 4
Sponsor	Ohio State University
Enrollment	1,572 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Singleton gestation. Twin reduction to singleton, either spontaneously or therapeutically, is eligible if it occurred before 14 weeks gestational age.
- Age 18 years or older
- Gestational age at randomization between 20 0/7 - 33 6/7 weeks based on project gestational age.
- GDM diagnosis less than or equal to 33 6/7 weeks based on project gestational age.
- Requires medication for glucose control defined as a 30% elevated glucose values (either fasting or postprandial or both) prior to randomization per determination of the provider or documented in the medical record.

... and 1 more (see full listing online)

### Exclusion (11)

- Renal disease (serum creatinine  $>1.3$  mg/dL) due to the potential impact of metformin on renal function.
- Major structural malformation of the fetus.
- Known fetal aneuploidy based on invasive testing or positive for aneuploidy on cell-free fetal DNA screening.
- Contraindication to metformin or insulin, including: history of lactic acidosis, intractable nausea and vomiting, prior documented allergy and/or anaphylaxis.
- For individuals with GDM diagnosed  $<20$  0/7 weeks, documented A1c  $>6.5\%$  within prior 6 months.

... and 6 more (see full listing online)

## Locations (21 total)

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University of Alabama, Tuscaloosa, Alabama, United States  
Cedars Sinai Medical Center, Los Angeles, California, United States  
University of California San Francisco, San Francisco, California, United States  
... and 18 more locations

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<https://clinicaltrials.gov/study/NCT06445946>

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