

Inhaled Insulin vs Rapid-acting Injections for Post-meal Glucose Control in Women With Gestational Diabetes

NCT06535789

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Jaeb Center for Health Research
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (8)

- Ability to provide informed consent for study participation
 - Age ≥ 18 years and < 41 years old
 - Singleton pregnancy at 24-34 weeks gestation
 - Diagnosis of GDM via standard 1-step or 2-step criteria
 - Treated with an insulin regimen that includes a RAA bolus of any type for breakfast, with a dose < 20 units
- ... and 3 more (see full listing online)

Exclusion (13)

- Type 1 diabetes or type 2 diabetes
 - HbA1c $\geq 6.5\%$, FBG ≥ 125 mg/dl or 2-hr glucose ≥ 200 mg/dL on 75g OGTT, or random plasma glucose ≥ 200 mg/dL (consistent with pre-existing diabetes and not GDM diagnosis)
 - Current use of any non-insulin glucose lowering medication
 - Using TI (Afrezza), regular insulin, or ≥ 20 RAA units at breakfast (NPH is permissible)
 - Peak expiratory flow $< 80\%$ predicted as measured by peak flow meter
- ... and 8 more (see full listing online)

Locations (5 total)

Sansum Diabetes Research Institute, Santa Barbara, California, United States
University of Colorado Anschutz Medical Campus, Aurora, Colorado, United States
Icahn School of Medicine at Mount Sinai, New York, New York, United States
... and 2 more locations