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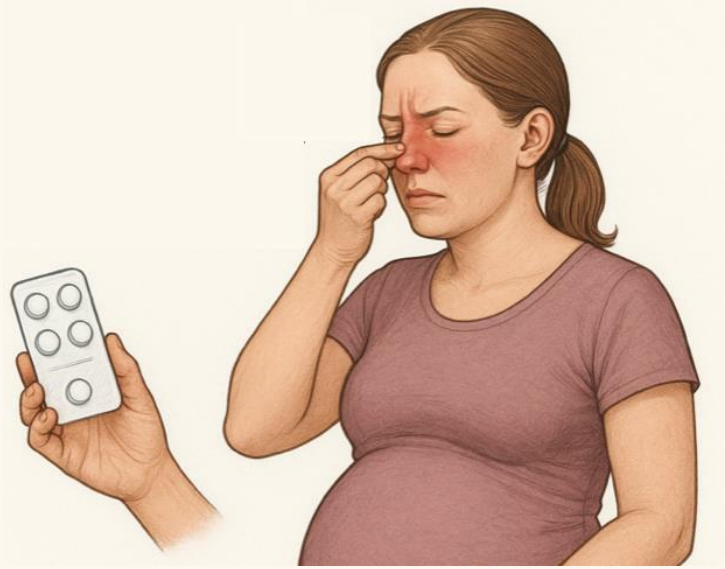
THESSALONIKI, GREECE
E-Poster 56

Exposure to Pseudoephedrine During Pregnancy and Major Congenital Malformations

A large population-based cohort study



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Introduction & Objective

Background

Pseudoephedrine (PSE) is a common decongestant that works by stimulating adrenergic receptors, causing blood vessel constriction, bronchodilation, and CNS stimulation.

Usage in pregnancy: Up to 25% of pregnant women report using decongestants for nasal congestion.

Safety Concerns:

- Some studies suggest links to congenital malformations (gastroschisis, small intestinal atresia, hemifacial microsomia, limb reduction defects)
- Other research has found no increased risk

Study Objective

To examine the association between first-trimester pseudoephedrine use and major congenital malformations

Methods & Key Results

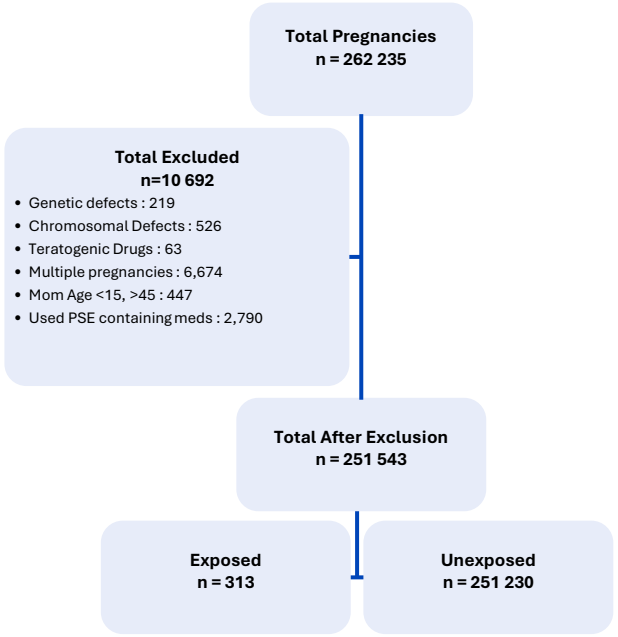
Study Design & Population

Design: Population-based cohort (Soroka Medical Center, 1999-2017)

Population: 251,543 singleton pregnancies, women aged 15-49

Exposure: High-dose PSE (Clarinase), 313 pregnancies (0.12%)

Study Flow:



Maternal Characteristics:

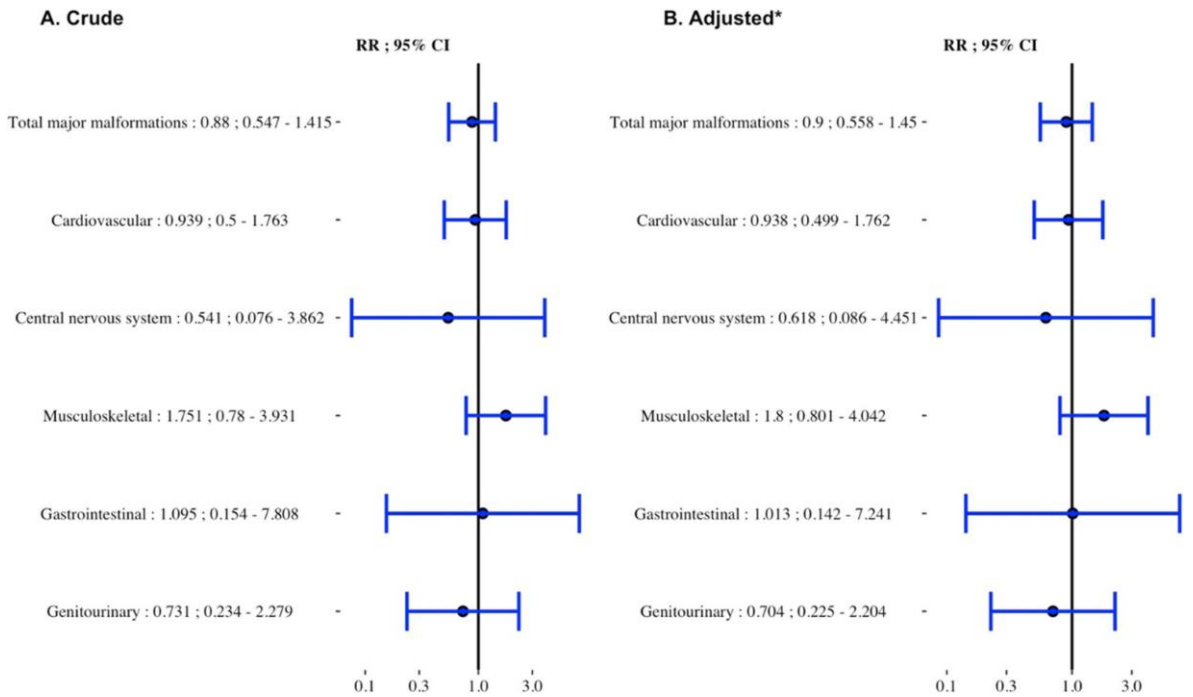
Characteristic	Exposed (n=313)	Unexposed (n=251,230)	P-value
Mean Age (years)	29.59	28.87	0.024
Ethnicity (% Jewish)	Higher %	Lower %	0.049
Gestational Diabetes	0.6%	0.1%	0.008

Key Findings

No increased risk of major congenital malformations

Adjusted RR = 0.90, 95% CI [0.558–1.45], p=0.66

Results by Organ System:



Sensitivity Analysis:

Ethnicity: Consistent results in both Jewish (RR = 0.934, 95% CI: 0.233–3.737) and Bedouin (RR = 0.493, 95% CI: 0.069–3.503) populations

Repeated pregnancies: Similar results in mixed-effects model (aRR = 0.476, 95% CI: 0.220–1.031)

Conclusion

First-trimester pseudoephedrine (PSE) exposure is NOT an independent risk factor for major congenital malformations

Clinical Implications

This large population-based study provides evidence supporting the safety of pseudoephedrine use during the first trimester of pregnancy.

These findings can help guide clinical decision-making for healthcare providers managing pregnant women with nasal congestion and other symptoms requiring decongestant treatment.

Study Strengths

- Large population-based cohort (251,543 pregnancies) Comprehensive assessment across organ systems
- Robust adjustment for potential confounders Consistent findings across different ethnic groups
- Validation in sensitivity analyses for recurrent pregnancies
- High-quality data linkage between multiple healthcare databases

Further Considerations

Future studies could examine different doses and durations of pseudoephedrine exposure

Results contribute to benefit-risk assessment for treating respiratory symptoms during pregnancy