



Bumpin' Up the Protection? RSV Vaccine in Pregnancy

CLINICAL QUESTION

How effective and safe is the respiratory syncytial virus (RSV) vaccine (Abrysvo™) when given during pregnancy?

BOTTOM LINE

The RSV vaccine (Abrysvo™), approved by Health Canada in pregnancy, reduces severe RSV infections (0.5% infection rate versus 1.8% placebo) and RSV hospitalizations (0.5% versus 1.3%) at 180 days in infants. Preterm births were numerically, but not statistically, higher with this vaccine versus placebo. Administration is limited to 32-36 weeks' gestation to mitigate this potential risk. Guidelines recommend nirsevimab for infants over prenatal vaccine where indicated.

EVIDENCE

- Focused on key randomized controlled trials (RCTs) of recombinant stabilized prefusion F protein subunit vaccine (RSVpreF, Abrysvo™): No systematic reviews of RSVpreF only. Results are for infants and statistically different unless specified. All industry funded.
- Efficacy: RSVpreF versus placebo, given 24-36 weeks gestation (mean: 31 weeks):^{1,2}

- 7392 pregnant women; 7128 infants (94% born 37-42 weeks);¹
 - Severe RSV infection:
 - At 90 days: 0.2% vs 0.9% (placebo), number needed to vaccinate (NNV)=143.
 - At 180 days: 0.5% versus 1.8% (placebo), NNV=77.
 - RSV hospitalization:
 - At 90 days: 0.3% vs 0.9% (placebo), NNV=167.
 - At 180 days: 0.5% vs 1.3% (placebo), NNV=125.
 - Limitations: RCT stopped early; limited RSV cases during study period (COVID-19 pandemic).
- 406 pregnant women; 403 infants (mean gestational age: 39 weeks);²
 - Severe RSV infection: 0.3% versus 2.9% placebo (no statistics reported).
 - Limitations: interim analysis, few events.
- Safety:
 - Preterm birth: 5.7% versus 4.7% (placebo), no statistical difference.¹
 - Observational study: 5.9% versus 6.7% (placebo), no statistical difference (administered at 32-36 weeks).³

CONTEXT

- In Canada, RSV causes:⁴
 - Childhood hospitalizations: ~2,500/year.
 - Mortality: 2-3 per 1000 hospitalized.
- Guidelines recommend:⁵
 - Nirsevimab (for infants) preferentially over prenatal RSVpreF vaccine citing greater efficacy and safety data. No direct comparison available.
 - RSVpreF administration: 32-36 weeks gestation (due to potential risk of preterm delivery).
- Preterm births: Safety signal with different vaccine (RSVpreF3).
 - Administered to 5328 pregnant women at 25-36 weeks gestation.⁶
 - Preterm birth: 6.8% versus 4.9% placebo, NNH=55.
 - Systematic review (three RSV vaccines, 4 RCTs): little/no difference in preterm birth.⁷
- Cost:⁸ \$280. Coverage varies by province.

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