



Preventing RSV in the elderly

CLINICAL QUESTION

What is the effectiveness and safety of Respiratory Syncytial Virus (RSV) vaccination in older adults?

BOTTOM LINE

For every ~380 medically-stable patients aged ≥ 60 , RSV vaccine prevents 1 RSV-associated lower respiratory tract disease (LRTD) per season over placebo. Study conducted during COVID-19 pandemic, potentially lowering baseline RSV incidence. Fatigue occurs in 34% versus 16% (placebo). General guidance suggests administration based on shared decision-making, particularly those at higher-risk (example long-term care, COPD), but higher-risk largely not studied.

EVIDENCE

- Statistically significant unless noted.
- Randomized controlled trial (RCT):¹ 24,966 adults ≥ 60 years given single-dose adjuvanted RSV prefusion F protein vaccine (RSVPreF3 OA vaccine, Arexvy[®]) or placebo. Planned 3-years; First RSV-season (6.7 months) results:
 - RSV-LRTD: 0.06% versus 0.3% (placebo); Number needed to vaccinate (NNV)=379.
 - "Severe" (≥ 2 clinical signs or investigator-assessed) RSV-LRTD: 0.008% versus 0.1% (placebo), NNV=781.
 - Injection site pain (61% versus 9%); fatigue (34% versus 16%): no statistics.

- RCT:² 34,284 adults ≥60 years given single-dose unadjuvanted RSVpreF vaccine (Abrysvo[®]) or placebo. First RSV-season (7 months) results:
 - RSV-LRTD (≥2 signs/symptoms): 0.07% versus 0.2% (placebo), NNV=742.
 - RSV-LRTD (≥3 signs/symptoms): 0.01% versus 0.08% (placebo), NNV=1360.
 - Local reactions: 12% versus 7%, no statistics.
- Systematic review: Published/unpublished two-season results of above RCTs (no statistics).³
 - RSV-LRTD relative efficacy:
 - Arexvy[®]: 83% (season 1) versus 56% (season 2).
 - Abrysvo[®]: 89% (season 1) versus 79% (season 2).
 - Actual events not reported.
 - Hospitalizations/deaths:
 - Arexvy[®]: 0.008% versus 0.04%.
 - Abrysvo[®]: 0.006% versus 0.02%.
 - No RSV-related deaths.
 - Safety:
 - Atrial fibrillation: 0.06%-0.08% versus 0.02%-0.03% (placebo).
 - 3 inflammatory neurologic events (example Guillain-Barré) with each Arexvy[®] (non-placebo-controlled trials) and Abrysvo[®] (placebo=0).
- Limitations: Industry-funded; studied during pandemic; immunocompromised, unstable comorbidities, and long-term care generally not included.

CONTEXT

- Arexvy[®] approved in Canada; ~\$250/injection.⁴
 - Abrysvo[®] not yet approved in Canada.
- RSV risk ≥50 years: 1.6-4.9%/year,⁵⁻⁷ declined during pandemic.^{5,8}
 - RSV hospitalization risk ≥65: 0.02%-0.26%/year.^{7,9-12}
 - Mortality 7-15% in RSV-hospitalized ≥60,^{7,12} increased with advancing age, long-term care, and comorbidities like chronic kidney disease/COPD.^{9,12}
- Risk of contracting influenza either 2-10x higher^{8,10-13} or similar to RSV.¹⁴
- US guidance recommends shared decision-making (aid available)¹⁵ for vaccinating ≥60.³

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