



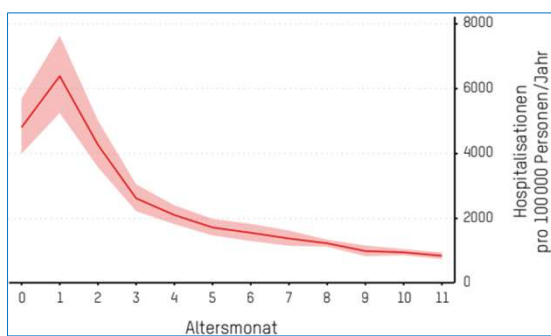
Respiratory syncytial virus (RSV) vaccines in adults and immunocompromised individuals

28th edition
 Allergology and Immunology Update AIU 2026
 Symposium III, Friday January 23, 2026
 Dr. med. Carla S Walti
 Oberärztin Infektiologie
 Universitätsspital Basel

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RSV- in infants

Age - Hospitalisations



Historically: considered a pathogen infecting children

Acute upper and lower tract respiratory tract illnesses

Leading cause of bronchiolitis in infants

CH pre-pandemic:

2.4 % of all infants hospitalised

3000 – 6000 hospitalisations per year

BAG_Bulletin_36-25_RSV_bf.pdf

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BAG / OFSP / UFSP – for infants

BAG Bulletin 36/25
1. September 2025

RSV ist im Winterhalbjahr die häufigste Ursache für Spitaleinweisungen bei Säuglingen.

Schützen Sie Ihr Baby mit einer RSV-Impfung.



Liegt Ihr Geburtstermin zwischen Oktober und März?

Ihre Impfung schützt Ihr Baby in den ersten Lebensmonaten.

Zielraum: In Schwangerschaftswoche 32+0 bis 36+0, mindestens 14 Tage vor der Geburt

Sprechen Sie mit Ihrer Ärztin oder Ihrem Arzt.

Maternal vaccination

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG



RSV ist im Winterhalbjahr die häufigste Ursache für Spitaleinweisungen bei Säuglingen.

Schützen Sie Ihr Baby mit einer RSV-Prophylaxe.



Optimaler Zeitpunkt:

- Neugeborene (geboren von Oktober bis März); kurz nach Geburt
- Säuglinge (geboren von April bis September); im Oktober
- besonders gefährdete Kinder unter 2 Jahren; im Oktober

Sprechen Sie mit Ihrer Ärztin oder Ihrem Arzt.

OR Passive immunisation infant

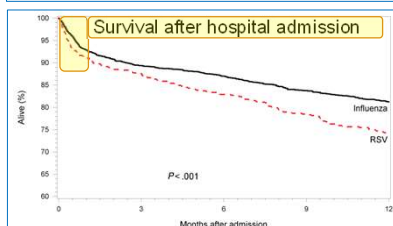
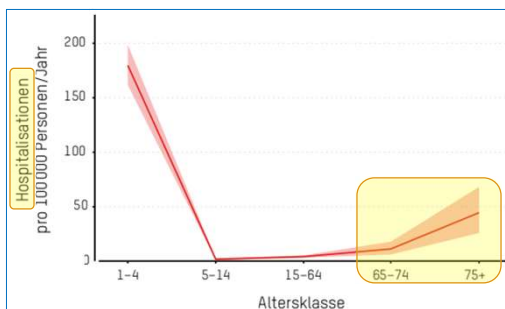
Schweizerische Eidgenossenschaft
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Bundesamt für Gesundheit BAG



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RSV – in adults



BAG_Bulletin_36-25_RSV_bf.pdf

Nguyen-Van-Tam JS. Burden of respiratory syncytial virus infection in older and high-risk adults: a systematic review and meta-analysis of the evidence from developed countries. Eur Respir Rev. 2022 Nov 15;31(166):220105.

Maggi S. Rate of Hospitalizations and Mortality of Respiratory Syncytial Virus Infection Compared to Influenza in Older People: A Systematic Review and Meta-Analysis. Vaccines. 2022;10(12):2092.

Ackerson B. Severe morbidity and mortality associated with respiratory syncytial virus versus influenza infection in hospitalized older adults. CID 2019;69:197-203.

Falsero AR. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005 Apr 28;352(17):1749-59.

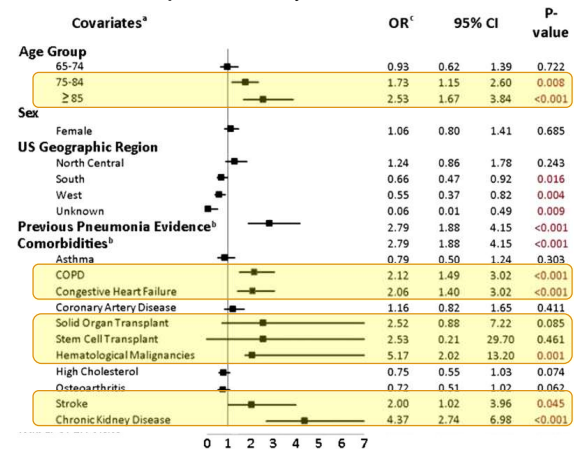
- **Frequency and relevance underestimated**
- **In older adults:** important cause of serious respiratory illness
 - 1%–10% of influenza-like acute respiratory tract illness
 - Rhinitis, sore throat, dry cough, fever, fatigue, conjunctivitis
 - Progress: bronchitis, viral pneumonia, otitis media, sinusitis
- Fewer office visits than influenza BUT
- In **hospitalised patients**, burden similar to influenza A:
 - similar length of stay (CH: 7.9 – 9.9 days)
 - ICU care 15 – 18%
 - mortality 8 %
 - home health service at discharge 31 %

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RSV – risk factors for adverse outcomes

- **Age, particularly those 75 years or older**
- **Frailty**
- **Coexisting conditions** such as
 - Pulmonary disease
 - Heart disease / hypertension
 - Neuro- / neuromuscular disease
 - Chronic kidney- / liver disease
 - Diabetes mellitus
 - Immunosuppression
 - Transplantation
 - i.e. early post-Tx, lung, and HCT

Predictors of hospitalisation, Wyffels V, Adv Ther 02/2020



Havers FP, Whitaker M, Melgar M. *Jama Netw Open.* 2024; Nov 13;7(11):e2444756.
 Li Y, Kulkarni D, Begler E, et al. *Infect Dis Ther.* 2023; 12: 1137–43. 4
 Cong B, Dighero I, Zhang T, Chung A, Nair H, Li Y. *BMC Med.* 2023; 21: 224. 5
 Branche AR, Saiman L, Walsh EE, et al. 2017–2020. *Clin Infect Dis.* 2022; 74: 1004–11. 6
 Prasad N, Walker TA, Waite B, et al. *Clin Infect Dis.* 2021; 73: e158–63.

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RSV – vaccine development

- Margo 2012
 - **Prefusion F-specific antibodies - dominant role in RSV-neutralization**
 - major target of the most potent virus neutralizing antibodies
- McLellan 2013
 - **Development of prefusion F-specific vaccine antigen**
 - More immunogenic and longer half-life than postfusion-F-antigen



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RSV vaccines

RSVpreF Abrysvo®

- Pfizer
- **≥ 60 yo + pregnancy**
- 1x Intramuscular
- **Protein based**
 - Stabilised **prefusion F** protein
 - **Bivalent** RSV A 60-µg and B 60-µg [Ontario and Buenos Aires genotypes]
- **Non-adjuvanted**

RSVPreF3 OA Arexvy®

- GSK
- **≥ 60 yo**
- 1x Intramuscular
- **Protein based**
 - Stabilised **prefusion F** protein
 - 120 µg of RSVPreF3 antigen RSV A (*cross-immunity to B*)
- **AS01_E-Adjuvanted**
 - 25 µg 3-O-desacetyl-4'-monophosphoryl lipid A
 - 25 µg Quilajaja saponaria Molina, fraction 21 (QS21)
 - Adjuvans **increased RSV-specific CD4+ T-cell** frequencies in older adults (infect termination)

mRNA-1345 mRESVIA®

- Moderna
- **≥ 60 yo, im**
- 1x Intramuscular
- **mRNA based**
- mRNA with 5'-Cap-structure coding for stabilised **prefusion F** glycoprotein of RSV A (*cross-immunity to B*)
- lipid nanoparticle–encapsulated
- **Shipped frozen**

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BAG / OFSP / UFSP - non-pregnant adults

AIM?



- Reduce severe RSV-disease and -hospitalisations in older adults and people with increased risk
- Reduce RSV burden on health care system

WHO?

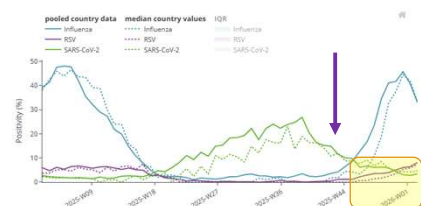


- **≥ 75 yo (complementary)**
- **≥ 60 yo with risk factors**
Immunodeficiency (disease / medication), pre-existing disease of lungs, heart-circulation, neurologic, neuromuscular, kidney, liver, hematologic, diabetes frailty, long-term care
- **≥ 18 yo very high risk (off-label)**

WHEN / WHAT?



- Starting in October, but latest prior to begin of RSV season
- 1. dose Abrysvo®, Arexvy®, mResvia®
- not paid from basic insurance, no data for repeated vaccine



BAG Bulletin 36-25_RSV_bf.pdf

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BAG / OFSP / UFSP – summary pivotal studies

Übersicht über die wichtigsten Phase-II/III-Wirksamkeitsstudien zu den drei RSV-Impfstoffen

Impfstoff (Herstellerfirma) Studienteilnehmende / Studiendetails (Referenz mit Direktlink)	Primärer Wirksamkeitsendpunkt* (VE)	Sekundärer Wirksamkeitsendpunkt* (VE)	
Abrysvo® (Pfizer) n = 34284; 60+ Jahre, mittleres Alter: 67 J , 52% m. Vorerkrankungen, mittleres follow-up 7 Monate [Walsh 2023]	RSV-bedingte LRTI mit ≥ 2 Symptomen 66,7%	RSV-bedingte LRTI mit ≥ 3 Symptomen 85,7%	RSV-bedingte ARI 62,1%
Arexvy® (GSK) n = 24960; 60+ Jahre, mittleres Alter: 69,5 J , 39% m. Vorerkrankungen, mittleres follow-up 6,9 Monate [Papi A. 2023]	RSV-bedingte LRTI 82,6%	Schwere** RSV-bedingte LRTI 94,1%	RSV-bedingte ARI 71,7%
mResvia® (Moderna) n = 35541; 60+ Jahre, mittleres Alter: 68,1 J , 29% m. Vorerkrankungen, mittleres follow-up 3,7 Monate [Wilson et al. 2024]	RSV-bedingte LRTI mit ≥ 2 Symptomen 83,7%	RSV-bedingte LRTI mit ≥ 3 Symptomen 82,4%	RSV-bedingte ARI 68,4%

* gemäss Studienprotokoll
** «Schwer» = LRTI-Episode, welche normale tägliche Aktivitäten verunmöglicht
LRTI = Lower respiratory tract disease (Untere Atemwegserkrankung); ARI = Acute respiratory infection (Akute Atemwegsinfektion)

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Abrysvo pivotal study (RENOIR-III)

ORIGINAL ARTICLE

Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults

Authors: Edward E. Walsh, M.D., Gonzalo Pérez Marc, M.D., Agnieszka M. Zareba, M.D., Ph.D., Ann R. Falsey, M.D., Qin Jiang, M.S., Michael Patton, B.Sc., Fernando P. Polack, M.D., et al., for the RENOIR Clinical Trial Group* Author Info & Affiliations

Published April 5, 2023 | N Engl J Med 2023;388:1465-1477 | DOI: 10.1056/NEJMoa2213836
VOL. 388 NO. 16 | Copyright © 2023

04/2023 prespecified interim analysis

Phase 3, 1:1 randomized, controlled, double-blind

P Adults **≥60 years of age**

healthy or “stable medical conditions”

Immunocompromised persons excluded

I Single intramuscular injection of RSVpreF vaccine

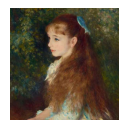
C Placebo

O **Efficacy** against RSV-associated illness in the **first RSV season after injection (08/2021-07/2022)**

- **Lower respiratory tract illness (LRTI)** with 2 or 3 symptoms

- **Acute respiratory illness (ARI)**

Safety



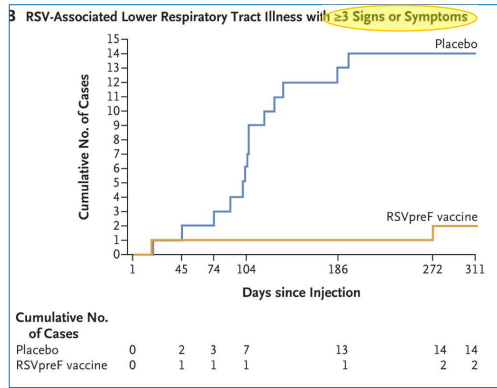
RENOIR, NCT05035212

Renoir, Kunsthaus Zürich

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Abrysvo pivotal study

Cases - Time



RSV-associated lower respiratory tract illness

RSV season + >14 days after vaccination + symptoms for >1 day + RSV RT-PCR

≥ 2 signs or symptoms LRTI

Vaccine efficacy 66.7% (96.66% CI, 28.8 – 85.8)

Placebo n= 33 / 17'069 3.58 cases / 1000 person-years
 Abrysvo n= 11 / 17'215 1.19 cases / 1000 person-years

≥ 3 signs or symptoms LRTI

Vaccine efficacy 85.7% (96.66% CI, 32.0 – 98.7)

Placebo n= 14 / 17'069 1.52 cases / 1000 person-years
 Abrysvo n= 2 / 17'215 0.22 cases / 1000 person-years

Similar efficacy across subgroups - but small subgroup sizes → wide confidence intervals

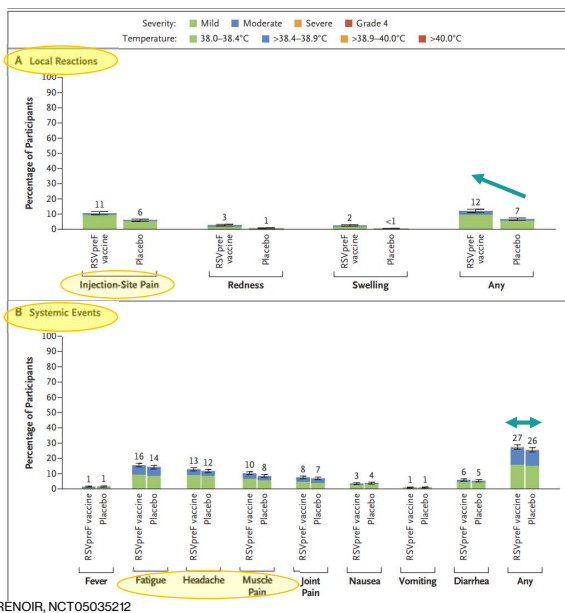
- age groups, prepecified high-risk conditions, RSV variants (mostly B)

- Low case numbers in study (pandemic)
- Number needed to vaccinate 773 and 1237

RENOIR, NCT05035212

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Abrysvo pivotal study



Safety

n = 7169

in ≥ 60 year old adults:

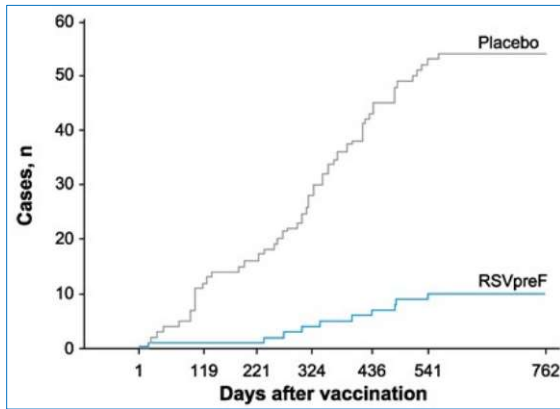
- more local reactions than placebo
- mostly mild-moderate reactions + self-limiting
- severe $\leq 0.7\%$ in both groups

RENOIR, NCT05035212

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Abrysvo second season

RENOIR Trial — RSVpreF Vaccine Efficacy over Two Seasons
 Published October 16, 2024 | N Engl J Med 2024;391:1459-1460 | DOI: 10.1056/NEJMc2311560
 VOL. 391 NO. 15 | Copyright © 2024



RENOIR, NCT05035212

Vaccine efficacy over 2 seasons against ≥ 3 signs or symptoms LRTI : 78%

	Season One	Season Two
	Vaccine Efficacy (95% CI)	Vaccine Efficacy (95% CI)
88.9% RSV LRTI, ≥3 symptoms	8/16,164	36/16,059
77.8% (51.4–91.1)		
65.1% RSV LRTI, ≥2 symptoms	39/16,164	88/16,059
55.7% (34.7–70.4)		
62.2% RSV-associated ARI	149/16,164	236/16,059
36.9% (22.2–48.9)		

- remains efficacious against more severe lower respiratory tract illness
- **No need for revaccination prior to second season**

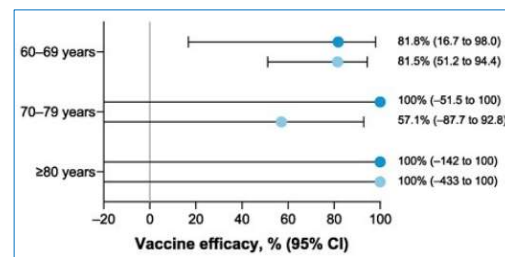
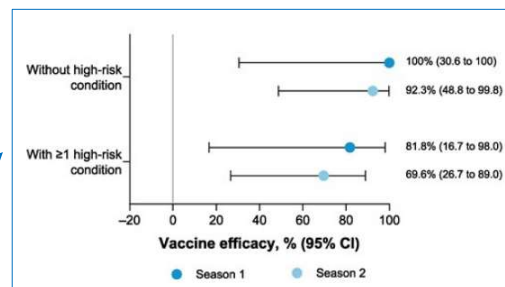
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Abrysvo additional outcomes

Efficacy, Immunogenicity, and Safety of the Bivalent Respiratory Syncytial Virus (RSV) Prefusion F Vaccine in Older Adults Over 2 RSV Seasons
 Edward E Walsh, Daniel Eiras, John Woodside, Qin Jiang, Michael Patton, Gonzalo Pérez Marc, Conrado Llapur, Mika Rämetsä, Yasushi Fukushima, Nazreen Hussien ... Show more
 Author Notes
 Clinical Infectious Diseases, ciaf061, https://doi.org/10.1093/cid/ciaf061
 Published 10 February 2025 | Article history

Efficacy over 2 seasons

- With and without high-risk conditions
- Not enough data in >70 yo



RENOIR, NCT05035212

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Arexvy pivotal study (AReSVi-006)

ORIGINAL ARTICLE f X in

Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults

Authors: Alberto Papi, M.D., Michael G. Ison, M.D., Joanne M. Langley, M.D., Dong-Gun Lee, M.D., Ph.D., Isabel Leroux-Roels, M.D., Ph.D., Federico Martinon-Torres, M.D., Ph.D., Tino F. Schwarz, M.D., Ph.D., for the AReSVi-006 Study Group. **Author Info & Affiliations**

Published February 15, 2023 | *N Engl J Med* 2023;388:595-608 | DOI: 10.1056/NEJMoa2209604
VOL. 388 NO. 7 | Copyright © 2023

02/2023 prespecified interim analysis

Phase 3, 1:1 randomized, controlled, double-blind

P Adults ≥60 years of age

Chronic conditions ok if “medically stable”

Immunocompromised persons excluded

I 1 x Arexvy

C Placebo

O Efficacy during 1 season against:

-- RSV-related lower respiratory tract disease (LRTD)

-- Severe LRTD

-- Acute respiratory infection (ARI)

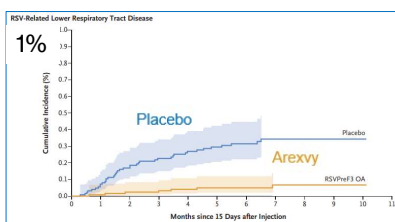
Safety

Immunogenicity

AReSVi-006 NCT04886596

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Arexvy pivotal study (AReSVi-006)



Efficacy against RSV-associated disease / ARI, season 1

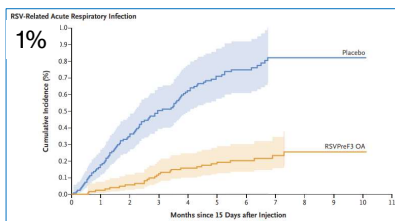
- Symptoms/signs for >1 day + RSV RT-PCR

LRTD

Vaccine efficacy 82.6% (96.95% CI, 57.9 – 94.1)

Placebo n= 40 / 12'499 5.8 cases / 1000 participant-years

Arexvy n= 7 / 12'467 1.0 cases / 1000 participant-years



«Severe» LRTD (prevents normal everyday activities)

Vaccine efficacy 94.1% (95% CI, 62.4 – 99.9)

Placebo n=17, Arexvy n=1

Acute respiratory infection (ARI)

Vaccine efficacy 71.7% (95% CI, 56.2 – 82.3)

Placebo n=98, Arexvy n=27

➤ Low case numbers in study (pandemic)

➤ Number needed to vaccinate:

LRTD 379, severe LRTD 782, ARI 177

Similar efficacy across
- underlying coexisting conditions
- RSV variants

LRTD	2 lower respiratory symptoms/signs or 3 lower respiratory symptoms
ARI	2 respiratory Or 1 systemic + 1 respiratory

AReSVi-006 NCT04886596

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Arexvy pivotal study (AReSVi-006)

Event	RSVPreF3 OA Group		Placebo Group	
	Participants no.	Incidence (95% CI) %	Participants no.	Incidence (95% CI) %
Solicited safety population	879		878	
Solicited reactions				
Any solicited reaction	632	71.9 (68.8–74.9)	245	27.9 (25.0–31.0)
Any grade 3 solicited reaction	36	4.1 (2.9–5.6)	8	0.9 (0.4–1.8)
Solicited injection-site reactions				
Pain	535	60.9 (57.5–64.1)	81†	9.3 (7.4–11.4)
Erythema	66	7.5 (5.9–9.5)	7†	0.8 (0.3–1.6)
Swelling	48	5.5 (4.1–7.2)	5†	0.6 (0.2–1.3)
Solicited systemic reactions				
Fever†	18	2.0 (1.2–3.2)	3	0.3 (0.1–1.0)
Headache	239	27.2 (24.3–30.3)	111	12.6 (10.5–15.0)
Fatigue	295	33.6 (30.4–36.8)	141	16.1 (13.7–18.7)
Myalgia	254	28.9 (25.9–32.0)	72	8.2 (6.5–10.2)
Arthralgia	159	18.1 (15.6–20.8)	56	6.4 (4.9–8.2)
Unsolicited adverse events				
Any unsolicited adverse event	131	14.9 (12.6–17.4)	128	14.6 (12.3–17.1)
Grade 3 unsolicited adverse event	12	1.4 (0.7–2.4)	12	1.4 (0.7–2.4)

Safety

- more solicited events with **Arexvy**
- most transient (1-2 days) + mild-to-moderate severity
- Fever rare
- no imbalance unsolicited AE and SAE
- No ADEM, GBS
- **Reactogenic vaccine**
- **but acceptable safety profile**

AReSVi-006 NCT04886596

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Arexvy 2nd RSV seasons

JOURNAL ARTICLE
Efficacy and Safety of Respiratory Syncytial Virus (RSV) Prefusion F Protein Vaccine (RSVPreF3 OA) in Older Adults Over 2 RSV Seasons
 Michael G Ison, Alberto Papi, Eugene Athan, Robert G Feldman, Joanne M Langley, Dong-Gun Lee, Isabel Leroux-Roels, Federico Martinon-Torres, Tino F Schwarz, Richard N van Zyl-Smit ... Show more
 Author Notes
Clinical Infectious Diseases, Volume 78, Issue 6, 15 June 2024, Pages 1732–1744,
<https://doi.org/10.1093/cid/ciae010>
 Published: 22 January 2024 Article history

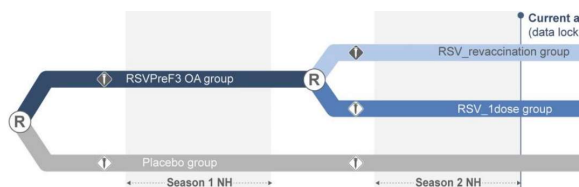
O Vaccine efficacy over 2 RSV seasons (21/22 and 22/23)

P same as in pivotal study

I Vaccinated patients were re-randomized (1:1) to receive pre-season 2

- **Second Arexvy dose**
- Placebo

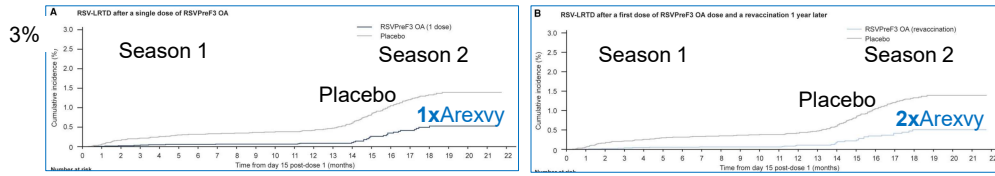
C Placebo



AReSVi-006 NCT04886596

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Arexvy Vaccine efficacy over 2 RSV seasons



	n LRTD/N	LRTD	«severe» LRTD	ARI
1x Arexvy	20 / 6227	67.2% (97.5% CI: 48.2–80.0%)	78.8% (95% CI: 52.6–92.0%)	52.7%
2x Arexvy	20 / 6242	67.1% (97.5% CI: 48.1–80.0%)	78.8% (95% CI: 52.5–92.0%)	60.3%

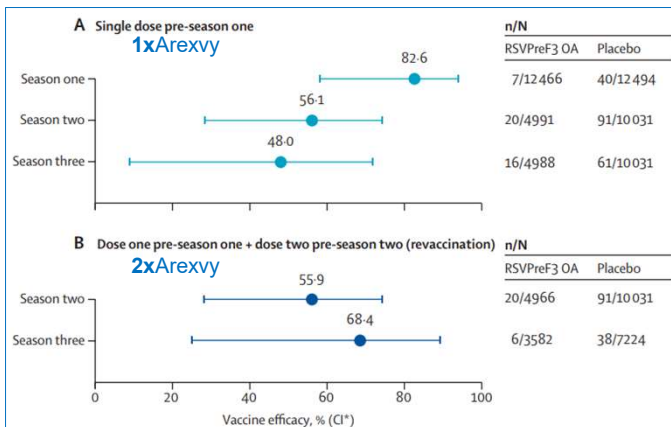
Efficacy shown among those with underlying medical conditions
 Reactogenicity/safety of the revaccination dose were similar to dose 1 (no ADEM, no GBS)
 Very few hospitalizations (n=6, 5 in placebo group); efficacy not evaluable

- No need for revaccination prior to second season
- Vaccine may be administered several months before the start of the RSV season

AReSVI-006 NCT04886596

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Arexvy Vaccine efficacy over 3 RSV seasons



- Single Arexvy dose efficacious against RSV-LRTD over three RSV seasons
- Despite decrease in efficacy over time
- Efficacy by revaccination 1 year later was in the same range as that of a single dose
- Very little data for old and frail patients

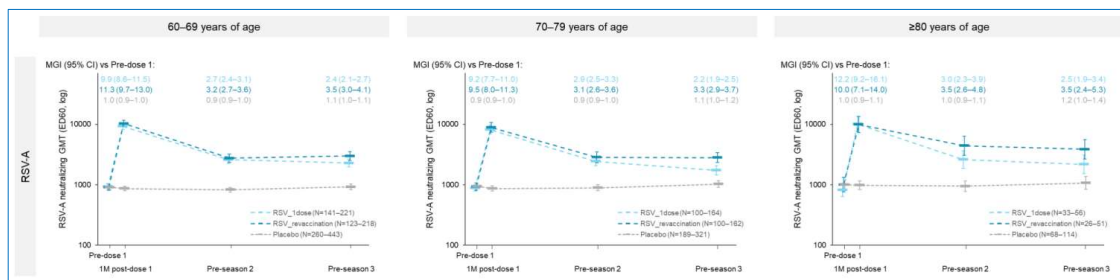
AReSVI-006 NCT04886596

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Arexvy Vaccine immunogenicity over 3 seasons

1 month after vaccination (GMC/GMT)

- RSVPreF3-specific **IgG** x **13** from baseline
- **Neutralizing** RSV AB x **9-10** from baseline
- Similar for: Arexvy only at baseline - Arexvy prior to season 2, RSV-A/-B, age groups,
- AB wane over time, but still higher than at baseline
- No booster effect with second dose



AReSVI-006 NCT04886596

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mResiva pivotal study ConquerRSV

Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults

Authors: Eleanor Wilson, M.D., Jaya Goswami, M.D., Abdullah H. Baqui, M.B., B.S., M.P.H., Dr.P.H., Pablo A. Doreski, M.D., Gonzalo Perez-Marc, M.D., Khalequ Zaman, M.B., B.S., Ph.D., Jorge Monroy, M.D., for the ConquerRSV Study Group* [Author Info & Affiliations](#)

Published December 13, 2023 | N Engl J Med 2023;389:2233-2244 | DOI: 10.1056/NEJMoa2307079
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Prespecified interim analysis

Phase 2-3, 1:1 randomized, controlled, double-blind

P Adults ≥60 years of age

healthy or “stable medical conditions”

Immunocompromised persons excluded

I Single intramuscular injection of mRNA-1345 vaccine

C Placebo

O **Efficacy** against RSV-associated disease in the first 12 months after injection (11/2021-11/2022)

- Lower respiratory tract disease (LRTD) with 2 or 3 symptoms

- Acute respiratory illness (ARI)

Safety

ConquerRSV NCT05127434

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mResiva pivotal study

>14 days – 12 months after vaccination

≥ 2 signs or symptoms LRTD

Vaccine efficacy 83.7 % (95.88% CI, 66.0 – 92.2)

Placebo n= 55 / 17'516 8.8 cases / 1000 person-years
 mResiva n= 9 / 17'572 1.4 cases / 1000 person-years

≥ 3 signs or symptoms LRTD

Vaccine efficacy 82.4 % (96.36% CI, 34.8 – 95.3)

Placebo n= 17
 mResiva n= 3

Acute respiratory illness (ARI)

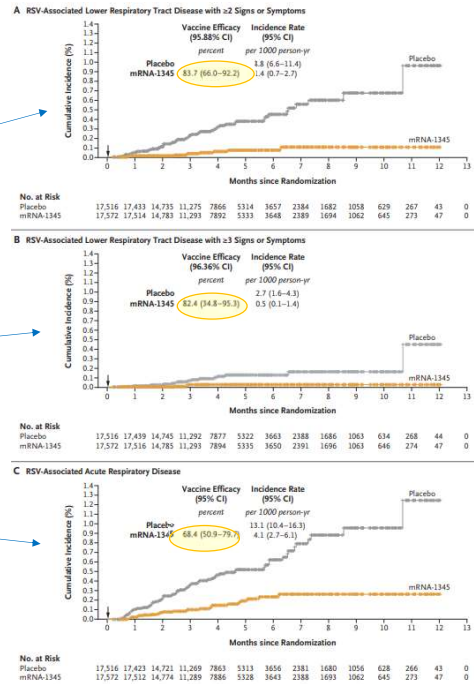
Vaccine efficacy 68.4 % (95% CI, 50.9 – 79.7)

Placebo n = 58 / 17'069
 mResiva n = 26 / 17'215

Same efficacy for RSV A and B

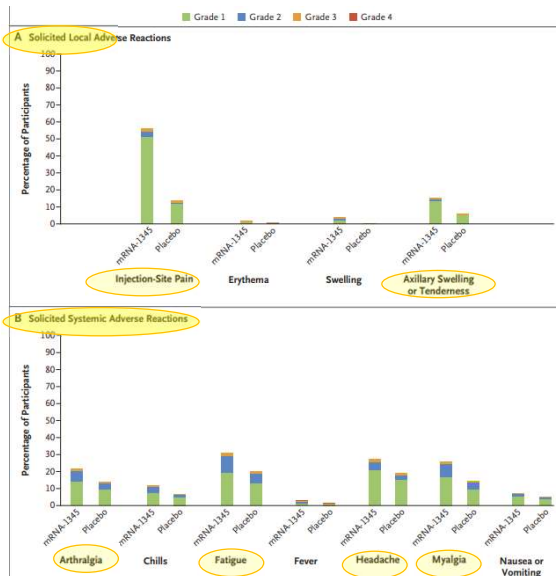
➤ Few cases per subgroup: No cases in ≥80 yo

ConquerRSV, NCT05127434



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mResiva pivotal study



ConquerRSV, NCT05127434

Safety

- more local and systemic reactions
- mostly mild-moderate + self-limiting
- Incidence decreased with age
- SAE: 4 injection related in each group
- No ADEM, no GBS
- No attributable deaths

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Pivotal studies - Abrysvo, Arexv, mResiva in ≥ 60 yo

- Vaccine effectiveness first season 67 – 94 %
- No need to re-vaccinate for second season
- Acceptable safety profile

BUT

- **Most data for ≥60 – 75 yo** → are they all at increased risk? → cost-effectiveness?
- **Very few data for ≥ 80 yo, comorbid, frail patients** → vaccine efficacy?
- **No data on immunocompromised patients** → despite increased risk
- Winter 2021/2022 with reduced RSV spread (Covid-19 measures) → low case numbers in pivotal studies → **Almost no data on important outcomes like hospitalisation / ICU admission / mortality**
- **Waning immunity** → when to revaccinate?

→ Real world data?

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First real world data in ≥60 yo

Payne AB, Lancet, 10/2024

- **Health records-based, USA, 8 states**
- **P** adults **≥ 60 years**, hospitalized for **respiratory illness**, underwent RSV testing, **winter 23/24**
- **I/C** Vaccine status
- **O** Vaccine effectiveness: estimated from odds of vaccination in RSV+ vs RSV-

	Total	Positive RSV test result (number [%])	Median interval since dose (days [IQR])	Unadjusted vaccine effectiveness (% [95% CI])	Adjusted* vaccine effectiveness (% [95% CI])
Immunocompetent—hospitalisation					
≥60 years				0 (ref)	0 (ref)
Unvaccinated	25816	1567 (6%)	NA	0 (ref)	0 (ref)
Vaccinated†	2455	35 (1%)	74 (44-109)	78 (69-84)	80 (71-85)
14-59 days earlier	934	7 (1%)	37 (26-48)	88 (75-94)	90 (79-95)
≥60 days earlier	1520	27 (2%)	100 (79-125)	72 (59-81)	73 (60-82)
OSK Arexv	1812	21 (1%)	73 (43-105)	82 (72-88)	83 (73-89)
Pfizer Abrysvo	642	33 (2%)	81 (48-116)	68 (44-82)	73 (52-85)
60-74 years				0 (ref)	0 (ref)
Unvaccinated	11048	670 (6%)	NA	0 (ref)	0 (ref)
Vaccinated	836	11 (1%)	75 (46-110)	79 (62-89)	84 (66-90)
≥75 years				0 (ref)	0 (ref)
Unvaccinated	14768	897 (6%)	NA	0 (ref)	0 (ref)
Vaccinated	1619	24 (1%)	74 (43-108)	77 (65-85)	79 (68-86)
Critical illness					
≥60 years				0 (ref)	0 (ref)
Unvaccinated	24506	257 (1%)	NA	0 (ref)	0 (ref)
Vaccinated	2425	5 (<1%)	74 (44-109)	81 (53-92)	81 (52-92)
With immunocompromise—hospitalisation					
≥60 years				0 (ref)	0 (ref)
Unvaccinated	7615	314 (4%)	NA	0 (ref)	0 (ref)
Vaccinated	820	10 (1%)	72 (43-108)	71 (46-85)	73 (48-85)

Vaccine effectiveness

Immunocompetent

Hospitalisation

80% (95% CI 71 – 85)

Age ≥ 75 yo

79% (95% CI 68 – 86)

ICU / death

81% (95% CI 52 – 92)

Immunocompromised

Hospitalisation

73% (95% CI 48 – 85)

solid malignancy, rheumatologic, hematologic malignancy, few transplant

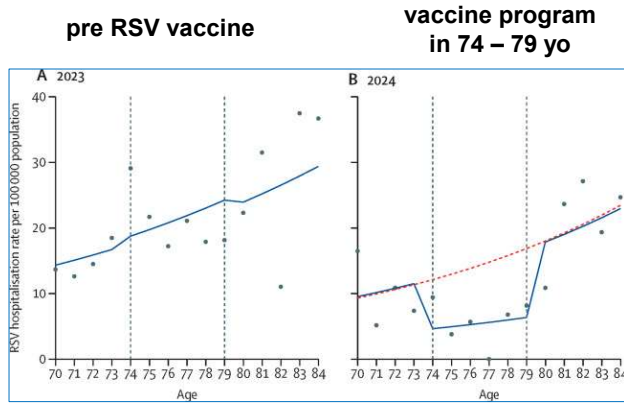
Critics: missing transparency on confounders

➤ **Reduces burden on health-care system**

Payne AB, Lancet 10/2024

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Real world data - hospitalisation



Hameed S, Lancet Infect Dis, Mar 2025

Scotland, population based (*regression discontinuity design*)

Vaccine program Abrysvo started 2024

- Only **ages 74–79** eligible for vaccination

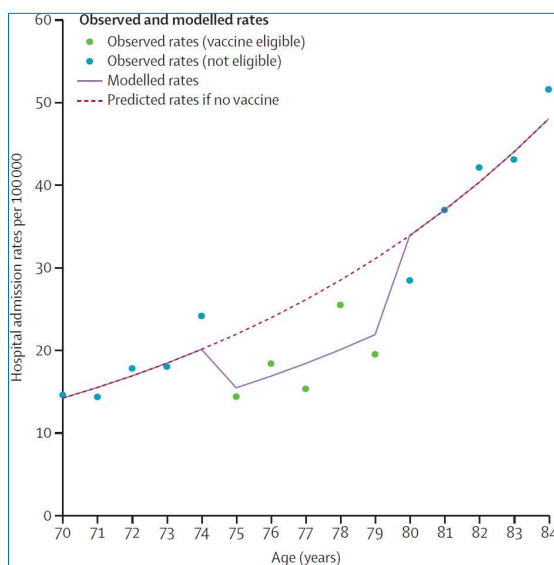
Impact on RSV-related hospitalisations

With a **vaccine coverage of 52 – 69 %** in the target group of

62 % reduction (95% CI 35 – 80) in 74-79 yo

27

Real world data - hospitalisation



Mensah AA., Lancet, Apr 2025

UK, population based analyses of new vaccine program (*regression discontinuity design*)

Vaccine programm started 2024:
only 75 - 79 yo

Impact on RSV-related hospitalisations

With a **vaccine coverage of 35 - 47%** in target group

30% reduction (95% CI 18–40, $p < 0.0001$) in target group

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More real world data – subgroups of interest

Symes R., Lancet Infect Dis, Nov 2025

UK, test-negative case-control study, **ages 75 – 79, hospitalised with ARI**, winter 23/24.

1006 patients: 324 vaccinated, 173 RSV cases.

Hospitalisation for RSV-ARI

VE 82 % (95% CI 71 – 90)

Subgroups of interest

- Severe disease VE 87 % (95% CI 75 – 94)
- COPD exacerbation VE 77 % (95% CI 42 – 93)
- Exacerbation heart/lung or frail VE 79 % (95% CI 48 – 93)
- **Immunosuppressed** **VE 73 % (95% CI 40 – 89)**
 - Def: Chemo, radio, SOT, HCT, HIV, immunosuppressive medication incl biologicals, ≥ 20 mg prednison, hematologic malignancies

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More real world data – 2 seasons

Surie D., JAMA, Aug 2025

USA, test-negative case-control study, 26 hospitals, **≥ 60 yo, hospitalised with ARI**, winter 23/24 and 24/25 (2 seasons). Recommendation: vaccinate all ≥ 75 yo, at risk ≥ 60 yo

6958 patients

- **Comorbidity**: 4459 hospitalised in prior year, 681 long-term care, 1829 immunocompromised
- 1030 vaccinated (mostly Arexvy and Abrysvo), 821 RSV cases.

Hospitalisation for RSV-ARI VE 58 % (95% CI 45 – 68) during 2 seasons

- **69%** (95% CI, 52 -81) **for same-season vaccination**
- **48%** (95% CI, 27 -63; $P = .06$) **for prior-season vaccination**

- **Lower vaccine efficacy in this comorbid real-world population**
- **Waning immunity?**

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More real world data – subgroups of interest

Subgroups of interest, 2 seasons

VE similar for Arexvy and Abrysvo

VE similar for RSV A and B

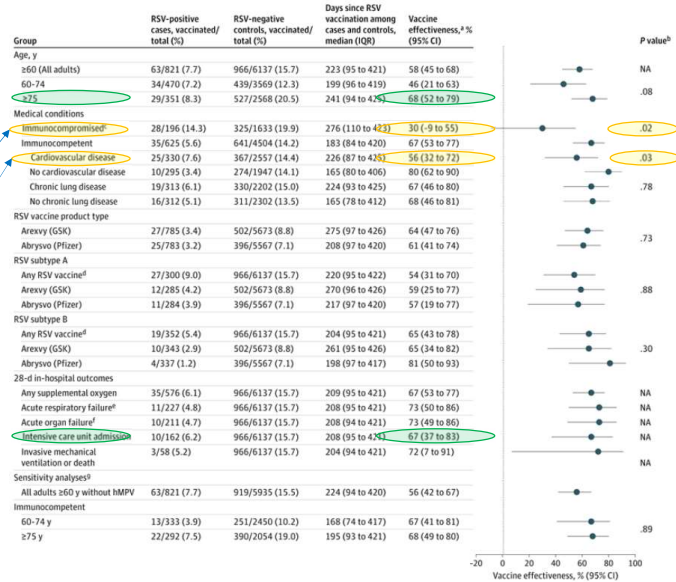
>75 yo **68 % (95% CI 52 – 79)**

ICU **67 % (95% CI 37 – 83)**

Significantly lower VE :

- **Immunocompromised**
30 % (95% CI -9 – 55)

- **Cardiovascular disease**
56 % (95% CI 32 – 72)



Surie D, JAMA 08/2025

RSV vaccines – real world data on safety

Fry SE, JAMA Netw Open, May 2025

USA, self-controlled case series on electronic health records, ≥60 yo

○ ITP or GBS within 6 weeks after vaccination

■ No excess risk of ITP. Guillain-Barré syndrome: excess of 5.2 cases (Arexvy, NS) or 18.2 cases (Abrysvo, significant) per 1 Mio doses of RSV vaccine

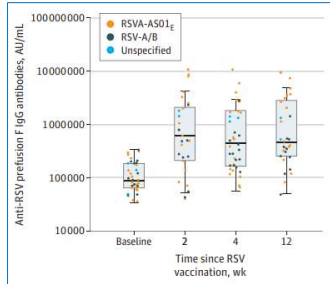
Cullen LA, Vaccines, Oct 2025

Scotland, retrospective observed versus expected and self-controlled case series, 74 – 80 yo

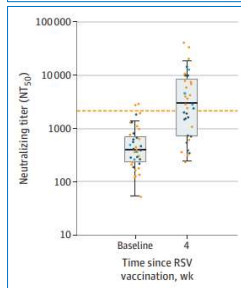
○ incidence of hospital admission for 39 conditions, including GBS in the 1–28-day post-vaccination period

■ increased risk of hospitalisation with GBS. Estimated excess risk of GBS: 46.1 cases per 1 million doses

RSV – first study in immunocompromised (mainly SOT)



PreF IgG



Neutralizing Ab

Karaba AH, JAMA, Feb 20205

Prospective cohort, John Hopkins University

P Immunocompromising condition

- 38 patients (31 SOT)
- enrolled 10/23-07/24

I Arexvy or Abrysvo

C None

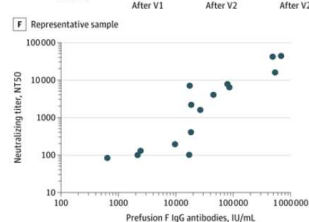
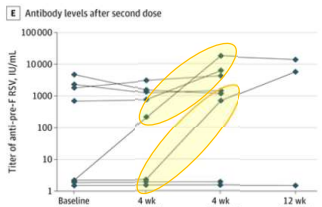
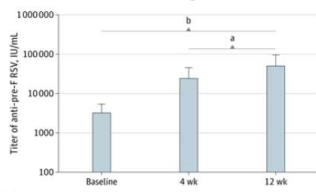
O Antibody response

Results

- **61 % Seroconversion** preF IgG
 - median (IQR) : x **4.21** (1.92-13.26)
- **58 % high-titer neutralization** ^[NT50]
 - Median (IQR) fold rise **6.97** (1.75-17.70)

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RSV – allogeneic HCT



Redjoul R, JAMA Netw Open, Sep 2025.

Prospective cohort, Paris

P 92 allogeneic HCT (≥3 mth post-Tx)

I non-adjuvanted Abrysvo

C None

O Antibody response

Results

- **Seroconversion** anti-pre-F RSV IgG
 - > 1 year post-allo HCT **9%** (3/32)
 - < 1 year post-allo HCT **75%** (45/60)

• **3 / 8 responded to second dose** (5 – 7 weeks later)

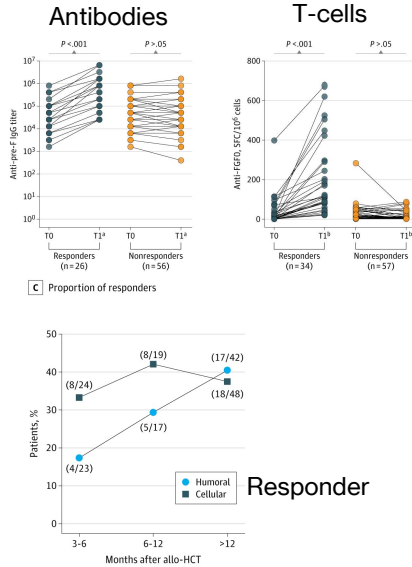
• **Good correlation nAB and anti-pre-F RSV IgG**

- Maybe adjuvanted vaccine better early post-Tx?
- Potential role for second dose in non-responder
- Anti-pre-F RSV IgG as surrogate endpoint for nAB

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RSV – allogeneic HCT



Loetscher / Walti, JAMA, Oct 2025. Prospective cohort, Basel CH

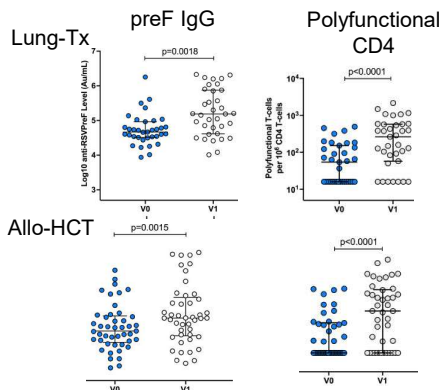
- P 94 allogeneic HCT recipients (≥3 mth post-Tx)**
- I adjuvanted Arexvy, 23/24**
- C None**
- O Antibody + cellular response**

Results

- **RSV-specific T-cell responses** **37 %**
 - Median anti-pre-F RSV IgG **x 16**
 - **Seroconversion anti-RSVPref-IgG** **32 %**
 - Month 3 – 6 **17 %**
 - Month 6 – 12 **29 %**
 - Month >12 **38 %**
 - Solicited AE comparable to pivotal study
 - 4 weeks after vaccination: **10 % new/worsening GvHD**
 - 12.9 months follow-up: **10 % break-through infection**
- Adjuvanted vaccine more immunogenic early post-Tx
- T cell response not associated with time from Tx → protect from severe disease?

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RSV – Lung-Tx and allogeneic HCT



Hall V, Clin Microbiol Infect, Sep 2026. Prospective cohort, Toronto

- P Lung-Tx (≥3 mth) and allogeneic HCT (≥6 mth)**
- I Arexvy**
- C None**
- O Antibody- + cellular response + safety**

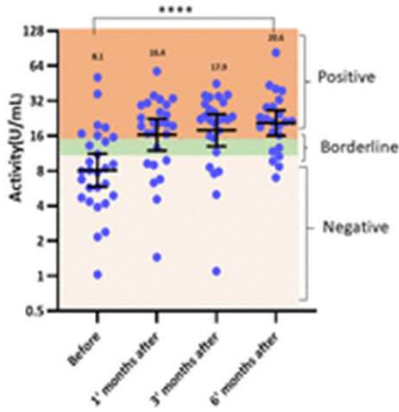
Patients 40 Lung-Tx (med 18 mth), 46 allo-HCT (med 18 mth)

Results

- **Seroconversion nAB** **LT 33.3 %, allo-HCT 48.7 %**
 - Neutralization Ab_[NT95] increased **LT x 3.0, allo-HCT x 1.3**
 - **Anti-RSV IgG increased** **LT x 3.3, allo-HCT x 2.3**
 - **RSV-specific CD4+ polyfunctional T-cell responses**
 - LT 28/35 (**80.0 %**), allo-HCT 30/42 (**71.4 %**)
 - **Seroconversion associated with time from Tx**
 - 3/40 LT developed RSV infection (191d follow-up). Well tolerated.
- modest seroconversion but robust CD4⁺ T-cell responses

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RSV – Lung-Tx



Levy, ERS, 2025, Conference Abstract.

P Lung-Tx

I Arexvy

C None

O RSV-specific antibody response

Patients

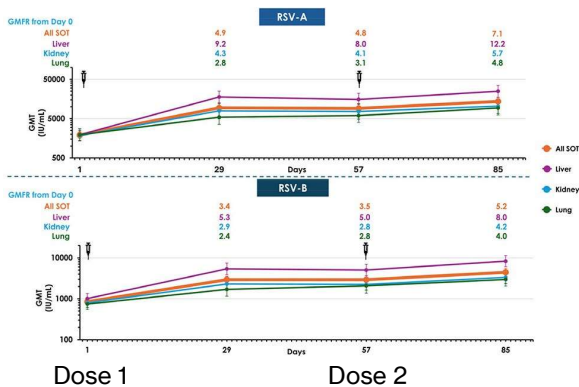
28, median time from Tx, 486 days (IQR 243-966)

Results

- **Sustained antibody response over 6 months**

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RSV –SOT recipient



Mayer EF, OFID, Jan 2026, Conference Abstract

Phase 3, evaluating 2 mResiva doses

P Solid organ transplant recipients ≥ 18 yo

- 150 SOT (50 kidney, 52 liver, 48 lung)
- Median age 57, range 24 – 80
- 26.7% received SOT < 2 years prior
- 80.6% concomitant tacrolimus ± mycophenolate ± steroids

I mResiva

C None

O nAB

Results

- after **Dose 1**, nAbs: **x 3.4 - 4.9** from baseline
- after **Dose 2**, nAbs **x 5.2 - 7.1** from baseline

- Liver – comparable to non-immunocompromised
- Lower in kidney and lung SOT
- Lower <2 years post-Tx
- Lower with MMF

➤ **Second dose in SOT?**

NCT06067230

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Economic analysis BAG

RSV vaccines every two years

- **Leads to gain in quality-adjusted life years**
- **But higher costs compared with no prevention**

- For those aged 75+
 - per quality-adjusted life year (QALY) CHF 244,000 - 292,000

- 60 - 75 with a high risk of complications
 - per quality-adjusted life year (ICER) CHF 281,000 - 334,000

- Budget impact of reimbursement over a two-year period:
 - CHF 80.58 - 81.58 million in the 75+ group
 - CHF 12.83 - 13.0 million 60 - 75

<https://www.bag.admin.ch/en/the-use-of-rsv-vaccination-in-older-adults>