Effectiveness and safety of Nirsevimab and Respiratory syncytial virus (RSV) vaccine: a living systematic review and meta-analysis of real-world evidence

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Table S 1. Search strategies

Ovid Embase (Embase Classic+Embase <1947 to March 11, 2025>)	
1	exp Human respiratory syncytial virus/
2	(Human respiratory syncytial virus or respiratory syncytial virus or RSV).ti,ab,kf.
3	1 or 2
4	exp respiratory syncytial virus vaccine/
5	exp vaccine/
6	exp vaccination/ or exp immunization/
7	(vaccin* or innoculat$ or jab or immuni#tion* or Nirsevimab or Monoclonal antibod* or PF?06928316 or RSVpreF or Prophyla* or Arexvy or Abrysvo or Mresvia).mp.
8	4 or 5 or 6 or 7
9	exp drug safety/
10	exp adverse event/ or exp drug monitoring/ or exp adverse drug reaction/
11	((adverse or side) adj2 (effect* or reaction* or event*)).mp.
12	(safety or harm* or disadvantage*).mp.
13	exp clinical effectiveness/
14	exp drug efficacy/
15	(effect* or efficac* or benefit* or advantage*).mp.
16	9 or 10 or 11 or 12 or 13 or 14 or 15
17	3 and 8 and 16
18	17 not ((exp animal/ or nonhuman/) not exp human/)
19	18 and (202212* or 2023* or 2024*).dd.
Ovid Medline (Ovid MEDLINE(R) ALL <1946 to March 11, 2025>)	
1	exp Respiratory Syncytial Virus, Human/
2	(Human respiratory syncytial virus or respiratory syncytial virus or RSV).ti,ab,kf.
3	1 or 2
4	Viral Vaccines/
5	exp Immunization/
6	(vaccin* or innoculat$ or jab or immuni#tion* or Nirsevimab or Monoclonal antibod* or PF?06928316 or RSVpreF or Prophyla* or Arexvy or Abrysvo or Mresvia).mp.
7	4 or 5 or 6
8	exp "Drug-Related Side Effects and Adverse Reactions"/ or exp Adverse Drug Reaction Reporting Systems/
9	exp Safety/
10	((adverse or side) adj2 (effect* or reaction* or event*)).mp.
11	(safety or harm* or disadvantage*).mp.
12	Comparative Effectiveness Research/
13	exp Vaccine Efficacy/
14	(effect* or efficac* or benefit* or advantage*).mp.
15	8 or 9 or 10 or 11 or 12 or 13 or 14
16	3 and 7 and 15
17	exp animals/ not humans.sh.
18	16 not 17
19	18 and (202212* or 2023* or 2024*).ed.
Ovid Global Health database (<1973 to March 11, 2025>)	
1	(Human respiratory syncytial virus or respiratory syncytial virus or RSV).ti,ab,hw.
2	exp vaccines/
3	exp immunization/
4	(vaccin* or innoculat$ or jab or immuni#tion* or Nirsevimab or Monoclonal antibod* or PF?06928316 or RSVpreF or Prophyla* or Arexvy or Abrysvo or Mresvia).mp.
5	2 or 3 or 4
6	exp adverse effects/
7	((adverse or side) adj2 (effect* or reaction* or event*)).mp.
8	(safety or harm* or disadvantage*).mp.
9	exp efficacy/
10	(effectiveness or efficac* or benefit* or advantage*).mp.
11	6 or 7 or 8 or 9 or 10
12	1 and 5 and 11
13	12 and (202212* or 2023* or 2024*).dp.

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Table S 2. Characteristics of the included studies (n=50)

Study	Intervention	Country	Study period	Study design	Target population for intervention	Study population	Study setting	Total N*	Immunised N	Population demographics
Nirsevimab and/or RSV maternal vaccine										
Agüera *et al.* (2024)[1]	Nirsevimab	Spain, Andorra	Nov 2023 - Feb 2024	Test-negative case control study	Infants <6 months old	Infants <12 months old, hospitalised with bronchiolitis	Secondary care	234	72	Median (IQR) age: 3.6 (1.5-8.1) months; 41% females; 73% had no comorbidities
Alejandre *et al.* (2024)[2]	Nirsevimab	Spain	Pre-seasons: 2010-2023 2023/24: Oct 1, 2023 - Feb 4, 2024	Interrupted time series	Infants <6 months old	Infants <10 months old, hospitalised at ICU with bronchiolitis	Secondary care	1531 (2023/24: 73; 2010-2023: 1458)	35/52 (eligible for nirsevimab)	Median (IQR) age: 80 (40-275) days post-nirsevimab; 47% females; 68% had no comorbidities
Andina Martínez *et al.* (2024)[3]	Nirsevimab	Spain	Pre-seasons: 2018-2023 2023/24: Nov 1, 2023 - Jan 31, 2024	Interrupted time series	Infants <6 months old (extended catch-up); <3 months old (limited catch-up); born during RSV season (no catch-up) depending on region in Spain	Infants <6 months old, with acute bronchiolitis seen at emergency department or hospitalised	Secondary care	84747 paediatric care encounters (2023/24: 17678 2018-2023: 67069)	331/608 (admissions)	NA (no population demographics provided)
Ares-Gómez *et al.* (2024)[4]	Nirsevimab	Spain	Sep 25 - Dec 31, 2023	Cohort study	Children 6-24 months old with high-risk factors	6-24 months old children with high-risk conditions	Secondary care	10259	9408	Median (IQR) age: 4.0 (2.0-6.0) months; 49% females
Assad *et al.* (2024)[5]	Nirsevimab	France	Oct 15 - Dec 10, 2023	Prospective matched case-control study	Infants <8 months old (newborns prioritised due to shortages)	Infants <12 months old, hospitalised with RSV-associated ARI	Secondary care	1035	157	Median (IQR) age for cases: 3.1 (1.8-5.3) months, for controls: 3.4 (1.6-5.6) months; 46% females
Barbas Del Buey *et al.* (2024)[6]	Nirsevimab	Spain	Oct 1, 2023 - Feb 29, 2024	Cohort study	Infants <6 months old	Infants <10 months old	Primary & secondary care	37067	29684	Median (IQR) age: 6.26 (4.46) months; 48% females
Cantais *et al.* (2024)[7]	Nirsevimab	France	Pre-seasons: 2022/23 2023/24: Sep 2023 – Feb 2024	Interrupted time series	Newborns at maternity wards born after September 15, 2023 (because of shortages)	Infants <6 months old	Primary & secondary care	1542 (2022/23: 794 2023/24: 748)	572/748 (2023/24)	NA (no population demographics provided)
Carcione *et al.* (2025)[8]	Nirsevimab	Australia	Apr 2, 2024 - Jul 31, 2024	Cross-sectional study	Children born on or after October 1, 2023, and high-risk	Infants born after October 1, 2023 who received	Primary care	1195	1195	0-2 months: 28.8% 2-4 months: 16.2% 4-6 months: 31.6%

					children entering their 2nd RSV season	nirsevimab between April 2 to July 31, 2024				≥6 months: 23.4% 47.7% females
Carbajal *et al.* (2024)[9]	Nirsevimab	France	Oct 14, 2023 - Feb 29, 2024	Case control study	Infants <8 months old (newborns prioritised due to shortages)	Infants <12 months old seen at emergency departments	Secondary care	2786 (cases – 178, controls – 701)	879	43.7% females
Chauvel *et al.* (2024)[10]	Nirsevimab	France	Pre-seasons: 2015-2023 2023/24: Sep 15 - Dec 31, 2023	Interrupted time series	Newborns at maternity wards (because of shortages)	Infants <6 months old	Secondary care	846 (2015-2020: 640 2022/23: 123 2023/24: 83)	21/83 (2023/24) 21/41 (RSV-related hospitalised infants)	Median (IQR) age (2023/24): 76 (40-110) days; 54% females
Coma *et al.* (2024)[11]	Nirsevimab	Spain	Oct 1, 2023 - Jan 31, 2024	Cohort study	Infants <6 months old	<9 months old, hospitalised with RSV-associated LRTI	Primary & secondary care	26525	23127	Median (IQR) age: 88 (44-134) days for immunised, 106 (52-151) days for non-immunised; 49% females
Consolati *et al.* (2024)[12]	Nirsevimab	Italy	Pre-seasons: 2022/23 2023/24: May 1, 2023 - Feb 15, 2024	Interrupted time series	Infants <8 months old	Infants born between May 1, 2023, and Feb 15, 2024	Primary & secondary care	Unclear (2022/23: unclear; 2023/24: 556)	369/556 (total births in 2023/24)	NA (no population demographics provided)
Ernst *et al.* (2024)[13]	Nirsevimab	Luxembourg	Pre-seasons: 2022 2023: Sep 24 - Dec 31, 2023	Interrupted time series	Infants <9 months old; children <2 years old at high risk for severe respiratory infection	Children <3 years old, hospitalised with RSV-associated ARI	Secondary care	630 (2022: 389; 2023: 241)	28/241 (2023)	Mean (SD) age: 14.4 (12.9) months
Espeleta-Fox *et al.* (2024)[14]	Nirsevimab	Spain	Pre-seasons: 2017-2023 2023/24:Nov 2023 - Mar 2024	Interrupted time series	Infants <6 months old	Infants <12 months old, hospitalised at ICU with RSV-associated LRTI	Secondary care	435 (2017-2023:414; 2023/24: 21)	3/21 (2023/24)	Median (IQR) age: 235.5 (183) days for controls, 113 (186) days for cases; 43% females
Estrella-Porter *et al.* (2024)[15]	Nirsevimab	Spain	Oct 1, 2023 - Jan 9, 2024	Cohort study	Infants <6 months old	Infants <6 months old (born between Apr 1, 2023, and Jan 7, 2024)	Primary & secondary care	27362	24223	49% females
Ezpeleta *et al.* (2024)[16]	Nirsevimab	Spain	Oct 1, 2023 - Jan 28, 2024	Cohort study	Newborns at maternity wards	Infants <3 months old in community; infants <4 months old, hospitalised, at	Secondary care	1177	1083	Median (IQR) age: 38.5 (14-60) days; 46% females

						emergency department, or admitted to ICU due to RSV-associated LRTI				
Homo *et al.* (2024)[17]	RSV maternal vaccine	US	Oct 16, 2023 - Feb 29, 2024	Cohort study	Pregnant people between 32 weeks 0 days and 36 weeks 6 days gestation	Pregnant people between 32 weeks 0 days and 36 weeks 6 days gestation	Tertiary care	500	414	Median (IQR) maternal age: 30 (8) years; 48% of infants female
Jabagi *et al.* (2025)[18]	Nirsevimab	France	Sep 15, 2023 – Jan 31, 2024	Cohort study	Infants <12 months old, immunised at outpatient setting (born between Feb 6 and Sep 15, 2023)	Infants ≤12 months old hospitalised with RSV (eligible for nirsevimab in the outpatient setting born between Feb 6 to Sep 15, 2023)	Secondary care	82474	41319	Mean (SD) age: 4.4 (2) months for nirsevimab group, 4.5 (2) months for non-immunised group; 47.5% females
Jeziorski *et al.* (2024)[19]	Nirsevimab	France	Oct 27, 2023 - Feb 29, 2024	Cohort study	Infants entering their first RSV season from mid-September 2023 (due to supply shortages, limited to newborns in maternity wards from October)	Infants ≤12 months old hospitalised with acute bronchiolitis	Secondary care	1085	230	Mean (SD) age in months – 3.9 (2.7), 47.2% females
Jimeno Ruiz *et al.* (2024)[20]	Nirsevimab	Spain	Pre-nirsevimab seasons: 2018-2022, Oct 1 – March 31 Post-nirsevimab season: Oct 1, 2023 - Mar 31, 2024	Cohort study, interrupted time series	Infants <6 months old	Infants <12 months old, hospitalised with RSV-associated ARI	Secondary care	646 (2018-2022: 569; 2023/24: 77)	26	Mean (SD) age: 6.4 (4.3) months; 53% females
Lassoued *et al.* (2024)[21]	Nirsevimab	France	Sep 15, 2023 - Feb 1, 2024	Test-negative case control study	All infants <12 months age, born after February 6, 2023 (priority was given to newborns and high-risk children)	Infants <12 months age with diagnosis of bronchiolitis	Secondary care	883	239	Median (IQR) age in months: Cases - 7.2 (4.6-9.8), controls - 6.3 (4.7-8.2), 37.94% females

Lefferts *et al.* (2024)[22]	Nirsevimab	US	Oct 23, 2023 - Jun 30, 2024	Test-negative case control study	American Indian or Alaska Native children <20 months old	American Indian or Alaska Native children <28 months old with medically-attended ARI	Secondary care	472	227	Median (IQR) age: 9 (0-27) months; 47% females
Lenglart *et al.* (2025)[23]	Nirsevimab	France	Oct 1, 2023 - Feb 29, 2024	Test-negative case control study	Infants <8 months old (newborns prioritised due to shortages)	Infants <12 months old, seen at emergency department with first bronchiolitis	Secondary care	383	77	Median (IQR) age: 3.3 (2.0-5.5) months for cases, 2.0 (1.0-4.0) months for controls; 43% females
Levy *et al.* (2024)[24]	Nirsevimab	France	Pre-season: Sep 25 2022- Jan 15 2023 2023/24: Sep 15, 2023 - Jan 15, 2024	Interrupted time series	Infants <8 months old (newborns prioritised due to shortages)	Infants <12 months old, at primary care with RSV-related bronchiolitis	Primary care	3828 (Sep 25 2022- Jan 15 2023: 3429 2023/24: 399)	62/399 (2023/24)	NA (no population demographics provided)
López-Lacort *et al.* (2024)[25]	Nirsevimab	Spain	Oct 1, 2023 - Jan 10, 2024	Screening design and test negative case-control study	Infants <6 months old	Infants <9 months old, hospitalised with LRTI	Secondary care	166	115	44% under 3 months old
López-Lacort *et al.* (2025)[26]	Nirsevimab	Spain	Nov 1, 2023 - Feb 29, 2024	Test-negative case control study	Infants <6 months old	Infants <10 months old, at primary care with LRTI	Primary care	160	141	Median (IQR) age: 4.5 (3.0-6.0) months; 36% females; 11% born preterm (<37 weeks gestation)
Mallah *et al.* (2024)[27]	Nirsevimab	Spain	Sep 25, 2023 - Apr 15, 2024	Cohort study	Infants <6 months old	Infants <12 months old (born between Mar 31, 2023, and Mar 31, 2024)	Community	14476	13320	Median (IQR) age: 6.7 (3.7-9.6) months; 49% females; 7% born preterm (<37 weeks of gestation)
Marouk *et al.* (2025)[28]	Nirsevimab	France	Oct 2, 2023 - Dec 31, 2023	Cohort study	All infants born in February 2023, with priority given to newborns	Infants aged <3 months who visited six pediatric EDs with a clinical diagnosis of bronchiolitis	Secondary care	739	206	Median (IQR) age in days – nirsevimab group – 46 (30-66), non-immunised group – 55 (32-73)
Martinon-Torres *et al.* (2023)[29]	Nirsevimab	Spain	Sep 25 - Oct 15, 2023	Cohort study	Infants <6 months old	Infants <12 months old (born between Mar 31, 2023, and Apr 1, 2024)	Community	8667	7241	NA (no population demographics provided)
Molina Gutiérrez *et al.* (2024)[30]	Nirsevimab	Spain	Pre-season: 2022	Interrupted time series	Infants <6 months old	Infants <9 months old, seen at emergency	Secondary care	264 (2022: 212; 2023: 52)	19/52(2023)	37% females

			2023/24 Oct 2 - Dec 31, 2023			department with RSV-related ARI				
Moline *et al.* (2024a)[31]	Nirsevimab	US	Oct 1, 2023 - Feb 27, 2024	Test-negative case control study	Infants <8 months old	Infants <13 months, hospitalised with ARI	Secondary care	699	59	42% females; 21% preterm (born <37 weeks of gestation); 6% with a high-risk condition
Moline *et al.* (2024b)[32]	Nirsevimab	US	Pre-seasons: 2017-2020 2023/24: Sep 1, 2023 - Apr 30, 2024	Test-negative case control study, interrupted time series	Infants <8 months old	Infants <12 months old with medically attended ARI	Primary & secondary care	28643 (2017-2020: 19153; 2023/24: 9490)	442/2989 (2023/24)	Median (IQR) age: 15 (6-29) months; 43% females
Moreno-Perez *et al.* (2025)[33]	Nirsevimab	Andalusia, Spain	Apr 1, 2023 - Oct 1, 2023	Cohort study	All infants <6 months age	Hospitalised infants <6 months with RSV bronchiolitis related hospitalisation during October 1, 2023, and Feburary 29, 2024, divided into immunised and non-immunised groups	Secondary care	222	127	Median (IQR) age – 59 (71), 40.1% females, any baseline condition: 5.9%
Nunez *et al.* (2025)[34]	Nirsevimab	Spain	Apr 1, 2023 - Mar 31, 2024	Matched case-control study	Infants born on or after April 1, 2023	Hospitalised infants born on or after April 1, 2023, admitted to public hospitals due to LRTI, apnoea, or sepsis between October 1, 2023 to March 31, 2024.	Primary & secondary care	4757	4002	Median (IQR) age (days): catch-up cases group: 140 (97-190) at-birth immunisation cases group: 43 (27-61); 46.12% females
Paireau *et al.* (2024)[35]	Nirsevimab	France	Sep 15, 2023 - Jan 31, 2024	Test-negative case control study	Infants <8 months old (newborns prioritised due to shortages)	Infants <4.5 months old, admitted to ICU with bronchiolitis; infants <9.5 months with comorbidities	Secondary care	288	58	91% aged 0-3 months, 9% aged 4-8 months; 45% females; 88% ad no comorbidities

Perramon-Malavez *et al.* (2024)[36]	Nirsevimab	Spain	Pre-season: 2014-2023 2023/24	Interrupted time series	Infants < 6 months old	Infants <36 months old	Community	NA	NA	NA
Perramon-Malavez *et al.* (2025)[37]	Nirsevimab	Spain	Oct 1, 2023 - Jan 31, 2024	Cohort study	Newborns at maternity wards	Infants <4 months old	Secondary care	15341	14055	Median (IQR) age: 69 (10-122) days for immunised, 60.5 (10-122) for non-immunised; 48% females
Reina *et al.* (2024)[38]	Nirsevimab	Spain	Nov 27,2023 - Mar 31, 2024	Interrupted time series	Infants <8 months old as of 27 Nov 2023 (born after 1 Apr 2023)	Infants <6 months old attending emergency department with acute respiratory infection	Secondary care	581 (2022/23: 303; 2023/24: 278)	192/278 (2023/24)	NA
Son *et al.* (2024)[39]	RSV maternal vaccine	US	Sep 22, 2023 - Jan 31, 2024	Cohort study	Pregnant people between 32 weeks 0 days and 36 weeks 6 days gestation	Pregnant people who gave birth to singleton gestations at 32 weeks' gestation or later from Sep 22, 2023, to January 31, 2024	Community	2973	1011	Maternal median (IQR) age: 34.9 (32.4-37.7) years
Vazquez-Lopez *et al.* (2025)[40]	Nirsevimab	Spain	Dec 1 -Dec 26 for 2022 and 2023	Interrupted time series	All infants <6 months and high-risk infants <2 years age	Children under 2 years reporting to pediatric emergency departments of 30 participating hospitals from 12 Autonomous Communities with bronchiolitis	Secondary care	1300 (2022: 650; 2023: 650)	NA	NA
Xu *et al.* (2025)[41]	Nirsevimab	US	Oct 1, 2023 - May 9, 2024	Test negative case-control study	Infants <8 months old; infants 8-12 months old with a risk factor for severe respiratory infection	Children <19 months old with medically attended RSV-associated ARI	Primary & secondary care	3090	330	Median (IQR) age: 6.7 (3.6-9.7) months; 43% females
RSV vaccine for the elderly										
Bajema *et al.* (2025)[42]	RSV vaccine for the elderly	US	Sep 1 - Dec 31, 2023	Cohort study	Adults ≥60 years old	Adults ≥60 years enrolled in Veterans Health Administration (VHA)	Primary & secondary care	293704	146852	Mean (IQR) age: 74.4 (67.8-78.6) yeas, 5.8% females

Birabaharan *et al.* (2024)[43]	RSV vaccine for the elderly	US	May 3, 2023 - Oct 9, 2024	Cohort study	Adults ≥60 years old	Adults ≥60 years old	Community	357814	99822	Mean (SD) age: 72.5 (7.1) years for cases, 69.7 (8.1) years for controls; 58% females
Hameed *et al.* (2025)[44]	RSV vaccine for the elderly	UK	Aug 12 - Nov 27, 2024	Quasi-experimentalstudy	Adults aged 74-79 years old	Adults aged 74-79 years old	Secondary care	201891	201891	NA
Hause *et al.* (2024)[45]	RSV vaccine for the elderly	US	May 3, 2023 - Apr 14, 2024	Cohort study	Adults ≥60 years old	Adults ≥60 years old who received RSV vaccine	NA	19420 episodes	19420 (V-safe: 16220; VAERS: 3200)	V-safe – 59.7% females, VAERS – 69.9 females
Lloyd *et al.* (2025)[46]	RSV vaccine for the elderly	US	May 2023 - Jan 2024	Self-control case series	Adults aged >65 years enrolled in Medicare Fee-for-Service and Medicare Part D	Medicare FFS and Part D benificiaries aged >65 years who received RSVPreF3+AS01 or RSVPreF	Secondary care	3226689	3226689	Age at vaccine administration in years: 65-69 years – 18.83%, 70-74 years – 29.91%, 80-84 years – 15.24%, 85-89 years – 7.23%, 90+ years – 3.80%; 57.49% females
Nguyen *et al.* (2025)[47]	RSV vaccine for the elderly	Australia	Feb 29, 2024 - Sep 27, 2024	Cross-sectional	Adults aged >60 years	Adults aged >60 years in Australia who recieved RSVPreF protein vaccine within February 29, to September 27, 2024, and responded to the survey	NA	2013	2013	Median age (IQR): 75 (70-80) years, 61.95% females
Payne *et al.* (2024)[48]	RSV vaccine for the elderly	US	Oct 1, 2023 - Mar 31, 2024	Test-negative case control study	Adults ≥60 years old	Adults ≥60 years old hospitalised or at emergency department with LRTI	Secondary care	36706 hospitalisations	3275	Median (IQR) age: 76 (69–84) years at hospitalisation, 75 (67–82) years at emergency department visit; 53% females hospitalised, 55% females at emergency department
Surie *et al.* (2024)[49]	RSV vaccine for the elderly	US	Oct 1, 2023 - Mar 31, 2024	Test negative case control study	Adults ≥60 years old	Adults ≥60 years old, hospitalised due to ARI	Secondary care	2978	265	Median (IQR) age: 72 (66-80) years; 51% females; 24% immunocompromised; 96% chronic condition
Tartof *et al.* (2024)[50]	RSV vaccine for the elderly	US	Nov 24, 2023 - Apr 9, 2024	Test-negative case control study	Adults ≥60 years old	Adults ≥60 years old hospitalised or at emergency	Secondary care	7047	223	Mean (SD): 76.8 (9.6) years; 43% aged 60-74 years, 57% aged

						department with LRTI				75 or more years; 54% females

*Total number of immunised +non-immunised individuals; US=United States, UK=United Kingdom, NA=not available; SD=standard deviation; IQR=interquartile range

Table S 3. 'Risk of bias' quality assessment

1. **'Risk of bias' assessment for cohort studies (n=19 studies)**
   Q1: Were the two groups similar and recruited from the same population?
   Q2: Were the exposures measured similarly to assign people to both exposed and unexposed groups?
   Q3: Was the exposure measured in a valid and reliable way?
   Q4: Were confounding factors identified?
   Q5: Were strategies to deal with confounding factors stated?
   Q6: Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?
   Q7: Were the outcomes measured in a valid and reliable way?
   Q8: Was the follow up time reported and sufficient to be long enough for outcomes to occur?
   Q9: Was follow up complete, and if not, were the reasons to loss to follow up described and explored?
   Q10: Were strategies to address incomplete follow up utilized?
   Q11: Was appropriate statistical analysis used?

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Total	Total (%)	Risk of bias assessment
Ares-Gomez et al. (2024)[4]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Not applicable	Yes	8	72.7%	medium
Bajema et. al. (2025)[42]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11	100%	low
Barbas Del Buey et al. (2024)[6]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Yes	9	81.8%	low
Birabaharan et al. (2024)[51]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11	100.0%	low
Coma et al. (2024)[11]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Not applicable	Yes	9	81.8%	low
Estrella-Porter et al. (2024)[15]	Yes	Yes	Yes	Yes	Yes	No	Yes	Unclear	Yes	Not applicable	Yes	8	72.7%	medium
Ezpeleta et al. (2024)[16]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	10	90.9%	low
Hause et al. (2024)[45]	Yes	Yes	No	No	No	No	Unclear	Yes	Unclear	Unclear	No	3	27.3%	high
Homo et al. (2024)[17]	Yes	Yes	Unclear	No	No	Yes	Yes	Unclear	Unclear	Unclear	No	4	36.36%	high
Jabagi et. al. (2025)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11	100%	low
Jeziorski et al. (2024)[19]	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear	No	Yes	8	72.7%	medium
Jimeno Ruiz et al. (2024)[20]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	7	63.6%	medium
Mallah et al. (2024)[27]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Not applicable	Yes	9	81.8%	low
Marouk et. al. (2025)[28]	Yes	Yes	No	Yes	Not applicable	Yes	Unclear	Yes	Yes	Yes	Yes	8	72.7%	medium
Martinon-Torres et al. (2023)[29]	Yes	Yes	Yes	Unclear	No	Yes	Yes	Unclear	No	No	No	5	45.5%	high

Moreno-Perez et. al. (2025)[33]	Yes	Yes	Yes	Yes	Not applicable	Yes	Yes	Yes	Yes	Unclear	Unclear	8	72.7%	medium
Perramon-Malavez et al. (2025)[37]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	10	90.9%	low
Reina et al. (2024)[38]	Yes	Yes	Unclear	No	No	Unclear	Yes	Yes	Yes	Not applicable	Unclear	5	45.5%	high
Son et al. (2024)[52]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Unclear	No	Yes	8	72.7%	medium

2. 'Risk of bias' assessment for case-control studies (n=16 studies)
JBI criteria:

Q1: Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?
Q2: Were cases and controls matched appropriately?
Q3: Were the same criteria used for identification of cases and controls?
Q4: Was exposure measured in a standard, valid and reliable way?
Q5: Was exposure measured in the same way for cases and controls?
Q6: Were confounding factors identified?
Q7: Were strategies to deal with confounding factors stated?
Q8: Were outcomes assessed in a standard, valid and reliable way for cases and controls?
Q9: Was the exposure period of interest long enough to be meaningful?
Q10: Was appropriate statistical analysis used?

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total	Total (%)	Risk of bias assessment
Aguera et al. (2024)[1]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	8	80.0%	low
Assad et al. (2024)[5]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	100.0%	low
Carbajal et al. (2024)[9]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	8	80.0%	low
Lassoued et. al. (2024)[21]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	100.0%	low
Lefferts et al. (2024)[22]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	90.0%	low
Lenglart et al. (2025)[23]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	8	80.0%	low
López-Lacort et al. (2024)[25]	Yes	No	Yes	Yes	Yes	Unclear	Unclear	Yes	Unclear	Unclear	5	50.0%	high
López-Lacort et al. (2025)[26]	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Unclear	Yes	7	70.0%	medium
Moline et al. (2024a)[31]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	90.0%	low
Moline et al. (2024b)[32]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	8	80.0%	low
Nunez et. al. (2025)[34]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	9	90.0%	low
Paireau et al. (2024)[35]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	90.0%	low
Payne et al. (2024)[48]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	90.0%	low
Surie et al. (2024)[49]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	9	90.0%	low
Tartof et al. (2024)[50]	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	8	80.0%	low
Xu et al. (2024)[53]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	90.0%	low

3. 'Risk of bias' assessment for quasi-experimental (incl. interrupted time series) studies (n=12 studies)
JBI criteria:

Q1: Is it clear in the study what is the "cause" and what is the "effect" (i.e. there is no confusion about which variable comes first)?
Q2: Was there a control group?
Q3: Were participants included in any comparisons similar?
Q4: Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?
Q5: Were there multiple measurements of the outcome, both pre and post the intervention/exposure?
Q6: Were the outcomes of participants included in any comparisons measured in the same way?
Q7: Were outcomes measured in a reliable way?
Q8: Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed?
Q9: Was appropriate statistical analysis used?

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total	Total (%)	Risk of bias assessment
Alejandre et al. (2024)[2]	Yes	Unclear	Yes	Yes	No	Yes	Yes	Yes	Yes	7	77.8%	low
Andina Martinez et al. (2024)[3]	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	7	77.78%	low
Cantais et al. (2024)[7]	Yes	Unclear	Yes	Unclear	No	Yes	Unclear	Unclear	Unclear	3	33.3%	high
Chauvel et al. (2024)[10]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	8	88.89%	low
Consolati et al. (2024)[12]	Yes	Yes	Unclear	Yes	No	Yes	Yes	No	Yes	6	66.67%	medium
Ernst et al. (2024)[54]	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	6	66.7%	medium
Espeleta-Fox et al. (2024)[14]	Yes	Unclear	Unclear	Unclear	No	Yes	Unclear	Yes	Unclear	3	33.3%	high
Hameed et al. (2025)[44]	yes	yes	unclear	unclear	no	yes	yes	unclear	yes	5	55.56	medium
Levy et al. (2024)[24]	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Unclear	Yes	6	66.7%	medium
Molina Gutierrez et al. (2024)[30]	Yes	Yes	Yes	Yes	No	Yes	Yes	Unclear	No	6	66.7%	medium
Perramon-Malavez et al. (2024)[36]	Yes	Unclear	Yes	Unclear	No	Yes	Yes	Unclear	Yes	5	55.6%	medium
Vazquez-Lopez et. al. (2025)[40]	yes	yes	yes	yes	no	unclear	yes	unclear	yes	6	66.67	medium

4. 'Risk of bias' assessment for cross-sectional studies (n=2 studies)
JBI criteria:

Q1. Were the criteria for inclusion in the sample clearly defined?
Q2. Were the study subjects and the setting described in detail?
Q3. Was the exposure measured in a valid and reliable way?
Q4. Were objective, standard criteria used for measurement of the condition?
Q5. Were confounding factors identified?
Q6. Were strategies to deal with confounding factors stated?
Q7. Were the outcomes measured in a valid and reliable way?
Q8. Was appropriate statistical analysis used?

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Total	Total (%)	Risk of bias assessment
Carcione et al. (2025)[8]	Yes	Yes	Yes	Unclear	No	Not applicable	Unclear	Yes	4	50.0%	medium
Nguyen et. al. (2025)[47]	Yes	Yes	Yes	Yes	No	No	Not applicable	Yes	5	62.5%	medium

5. 'Risk of bias' assessment for case series (n=1 study)
JBI criteria:

Q1. Were there clear criteria for inclusion in the case series?
Q2. Was the condition measured in a standard, reliable way for all participants included in the case series?
Q3. Were valid methods used for identification of the condition for all participants included in the case series?
Q4. Did the case series have consecutive inclusion of participants?
Q5. Did the case series have complete inclusion of participants?
Q6. Was there clear reporting of the demographics of the participants in the study?
Q7. Was there clear reporting of clinical information of the participants?
Q8. Were the outcomes or follow up results of cases clearly reported?
Q9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?
Q10. Was statistical analysis appropriate?

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total	Total (%)	Risk of bias assessment
Lloyd et. al. (2025)[46]	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	8	80.0%	low

Table S 4. Summary of findings from the included interrupted time series studies

Study	Pre-seasons	Outcome	Reduction %*
Alejandre et al. (2024)	2010/11 to 2022/2023	LRTI-related ICU admission	45.4%
		RSV-related ICU admission	36.2%
		Artificial ventilation at PICU due to severe bronchiolitis	44.3%
		Use of catecholamins at PICU due to severe bronchiolitis	75.8%
		Detection of RSV and a co-infection at PICU	11.0%
		PICU admissions due to severe bronchiolitis with detected RV	6.9%
Andina Martinez et al. (2024)	2018/19 to 2022/2023	LRTI-related ED visits	57.7%
		Bronchiolitis-related ED visits	59.2%
		LRTI- related admission	63.1%
		LRTI- related ICU admission	63.1%
Cantais et al. (2024)	2022/2023	Age of first RSV infection (months)	2022/2023: median 4.5 (IQR 2.1-13.1) 2023/2024: median 8.1 (IQR 3.9-19.1)
		Age of hospital admission (months)	2022/2023: median 3.5 (IQR 1.6–6.9) 2023/2024: median 6.2 (IQR 3.4–10.6)
Consolati et al. (2024)	2022/2023	RSV-related admission	61.7%
Chauvel et al. (2024)	2015/2016 to 2019/2020 (pre-COVID-19)	RSV-related admission	IRR 0.45 (95%CI: 0.33, 0.62) (reference: pre-COVID-19
	2022/2023	RSV-related admission	IRR: 0.53 (95%CI: 0.36, 0.77) (reference: 2022/2023)
Ernst et al. (2024)	2022/2023	RSV-related admission	Age <5years: 38.0% Age <6months: 69.0%
		RSV-related ICU admission	Age <5years: 58.0% Age <6months: 68.0%
		Length of hospital stay (day)	2022/2023: mean 5.1 days (SD: 5.4) 2023/2024: mean 3.2 days (SD: 2.5)
Espeleta-Fox et al. (2024)	2017-2022	RSV-related ICU admission	68.0%
Jimeno Ruiz et al. (2024)	2022/2023	RSV-related LRTI admission	Age <6months: 54.6% Age <3months: 53.6% Age 3-6months: 56.3%
Levy et al. (2024)	2022/2023	All-cause bronchiolitis cases	Age <3months: 52.7% Age ≥3 to ≤12 months: 26.5% Age ≥13 months: 20.4%
Molina Gutierrez et al. (2024)	2022/2023	RSV-related ED visits	75.5%

		Age at ED presentation (months)	2022/2023: median 2.4 (IQR 1.2–4.8) 2023/2024: median 3.6 (IQR 1.2–4.8)
Moline et al. (2024b)	2017-2020	RSV test positive -in all settings	1.2% to 7.1%
		RSV test positive -in hospitalised	-1.8% to 7.1%
		RSV test positive -in ED	0.7% to 1.9%
		RSV test positive -in outpatient/urgent care	3.4% to 6.1%
		RSV-related hospitalisation	Age <2months: RR 1.09 (95% CI 0.93-1.26) Age 3-5 months: RR 1.12 (95% CI 0.94-1.34) Age 6-11 months: RR 1.14 (95% CI 0.93-1.37) Age 12-23 months: RR 1.32 (95% CI 1.10-1.57)
Perramon-Malavez et al. (2024)	2022/2023 2014-2020	LRTI-related primary care visits	2022/2023: 39.8% 2014/2020: 61.9%
	2022/2023 2021/2022 2020/2021	RSV-related primary care visits	2022/2023: 75.6% 2021/2022: 80.3% 2020/2021: 76.7%
Reina et al. (2024)	2022/2023	LRTI-related ED visits	19.1%
		RSV-related ED visits	82.9%
Vazquez-Lopez et. al. (2025)	2022	LRTI-related ED visits	41.6%
		LRTI-related hospital admission	55.4%
		RSV-related hospital admission	60.3%
		LRTI-related ICU admission	81.3%

*Data are % otherwise stated. ARI= acute respiratory illness, RSV= respiratory syncytial virus, IRR= incidence rate ratio, SD= standard deviation, IQR=interquartile range, RR=rate ratio, ED=emergency department

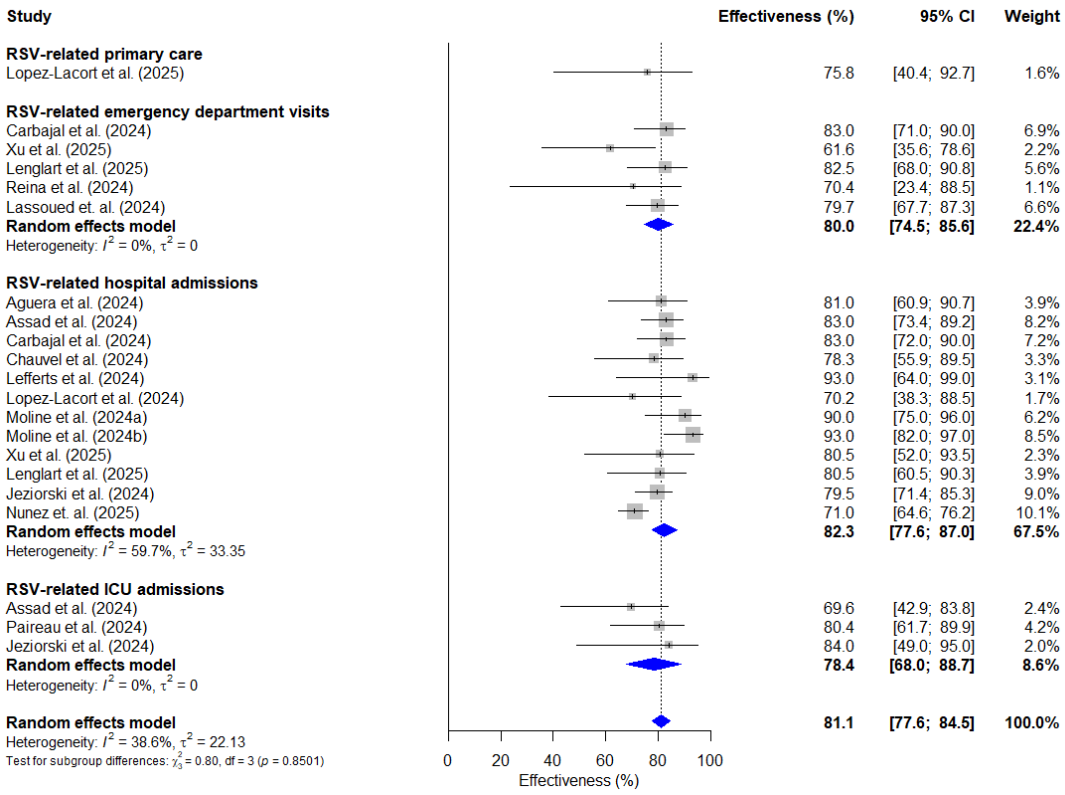
Table S 5. Safety of nirsevimab reported in the included studies.

Study	Adverse events	Percentage (%)
Ares-Gomez et al. (2024)	No severe adverse events	N/A
Ernst et al. (2024)	No severe adverse events	N/A
Ezpeleta et al. (2024)	No severe adverse events	N/A
Mallah et al. (2024)	No severe adverse events	N/A
Martinon-Torres et al. (2024)	No severe adverse events	N/A
Homo et al. (2024)	No severe adverse events	N/A
Consolati et al. (2024) (369 children)	Fever	6.4% (24/369)
	Local reaction	4.0% (15/369)
	Barely consolable crying	0.4% (1/369)
	Rash	0 % (0/369)
	No instances of major adverse effects	89.2% (329/369)
Carcione et al. (2025) (1195 for 410 children who received nirsevimab alone, and 785 children who received nirsevimab with 1 or more vaccinations)	Fatigue	14.4% (172/1195) / 7.1% (29/410)
	Local reaction	11.7% (140/1195) / 2.3% (9/410)
	Fever	10.6% (127/1195) / 3.4% (14/410)
	Gastrointestinal issues (vomiting/diarrhoea)	9.4% (113/1195) / 3.9% (16/410)
	Rash	1.9 % (23/1195)/ 1.7% (7/410)

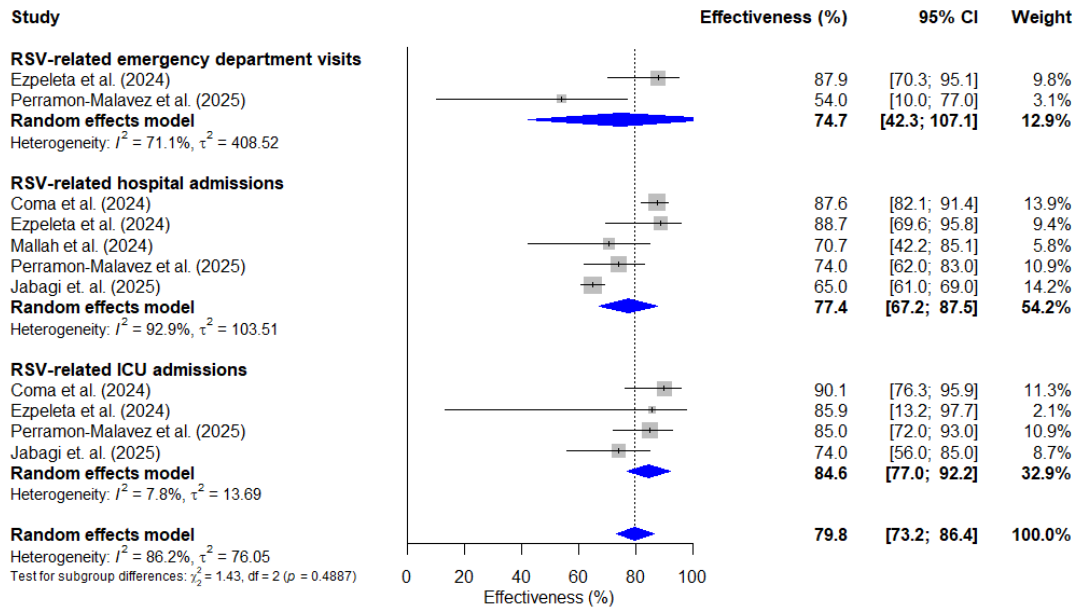
Note: N/A: not available

Figure S 1. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related healthcare utilisation, including primary care visits, emergency department visits, hospital admissions and intensive care unit admissions, using different effect estimates (ORs, HRs, and IRRs)

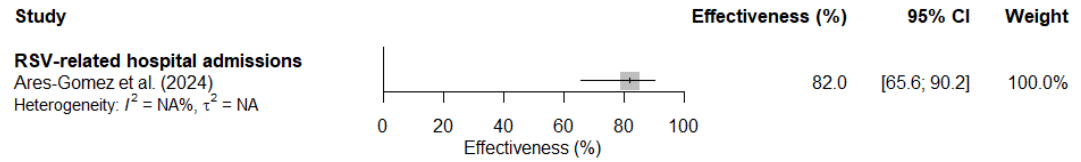
(a) Odds ratio



(b) Hazard ratio

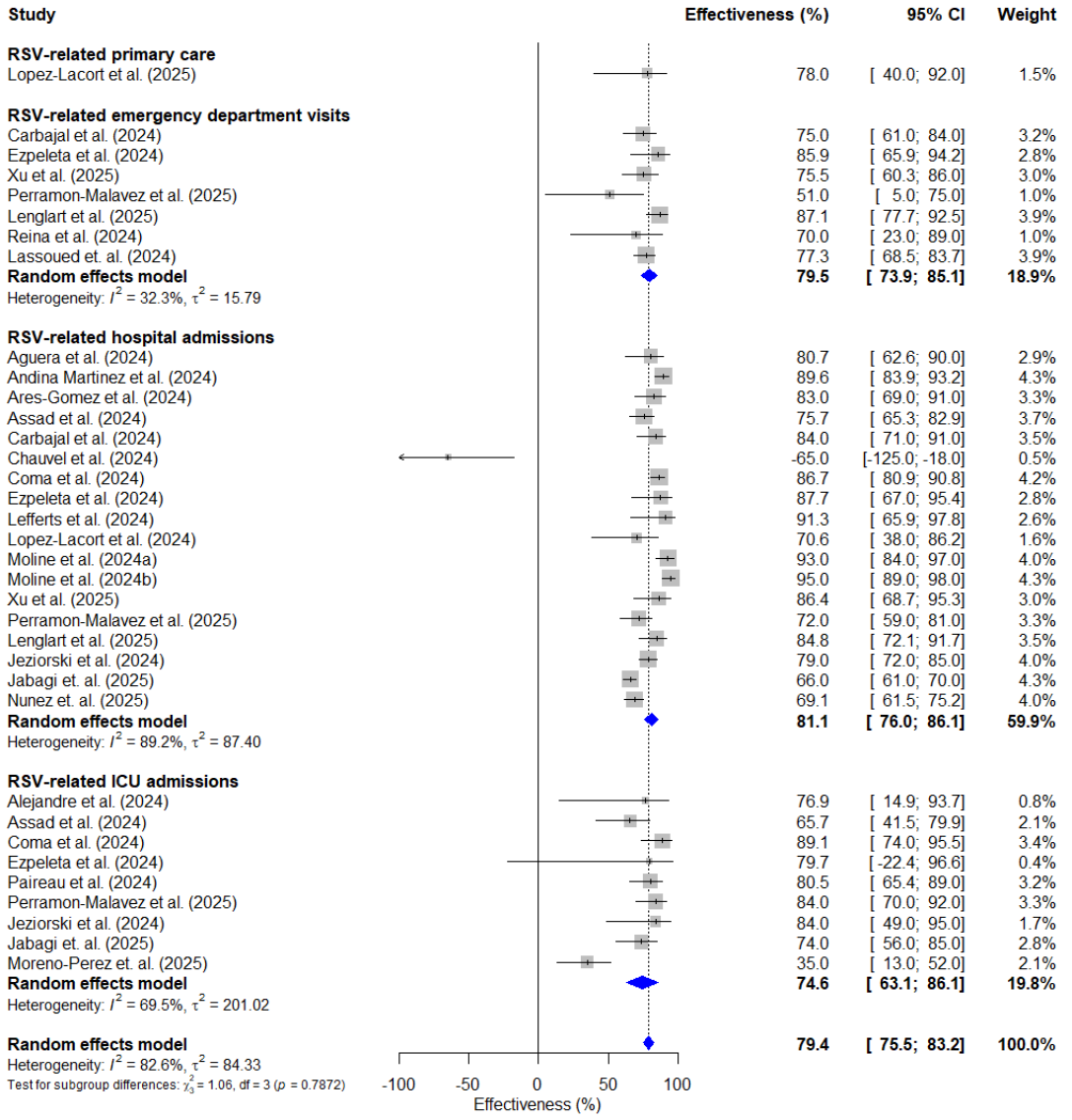


(c) Incident rate ratio



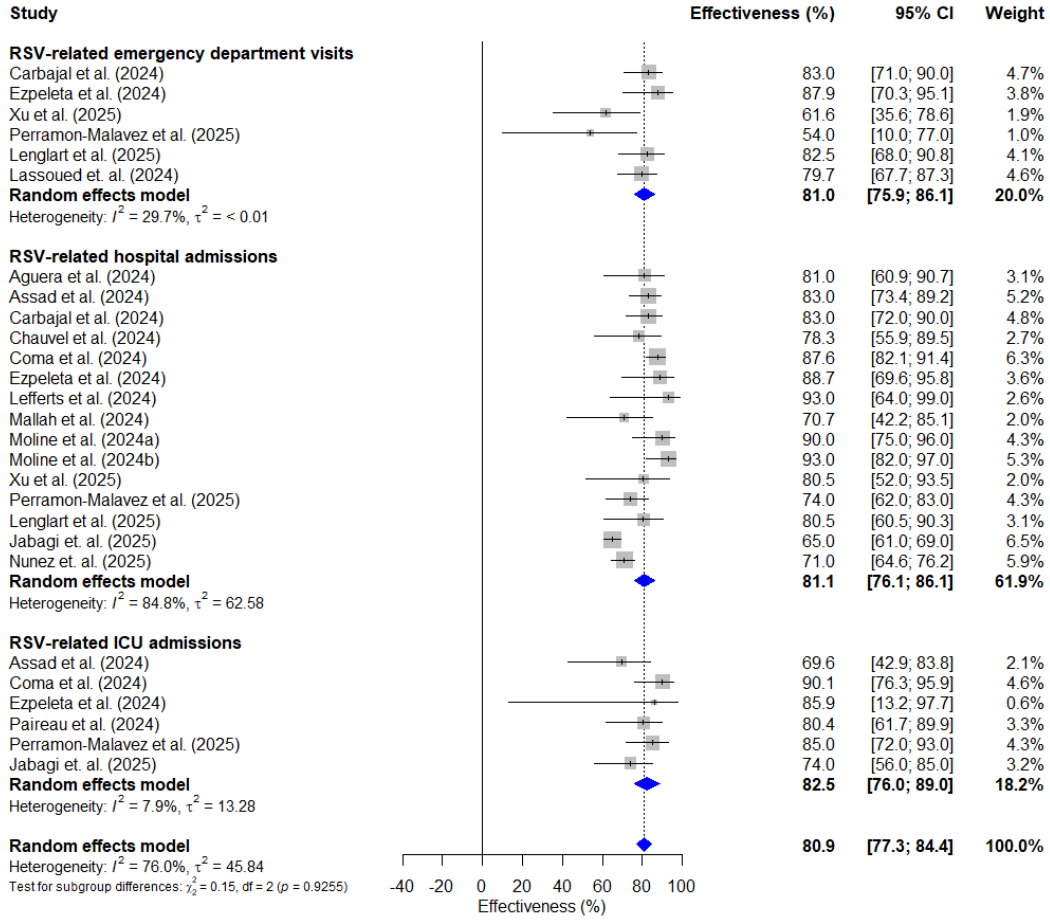
Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics

Figure S 2. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related healthcare utilisation, including primary care visits, emergency department visits, hospital admissions and intensive care unit admissions, using unadjusted estimates



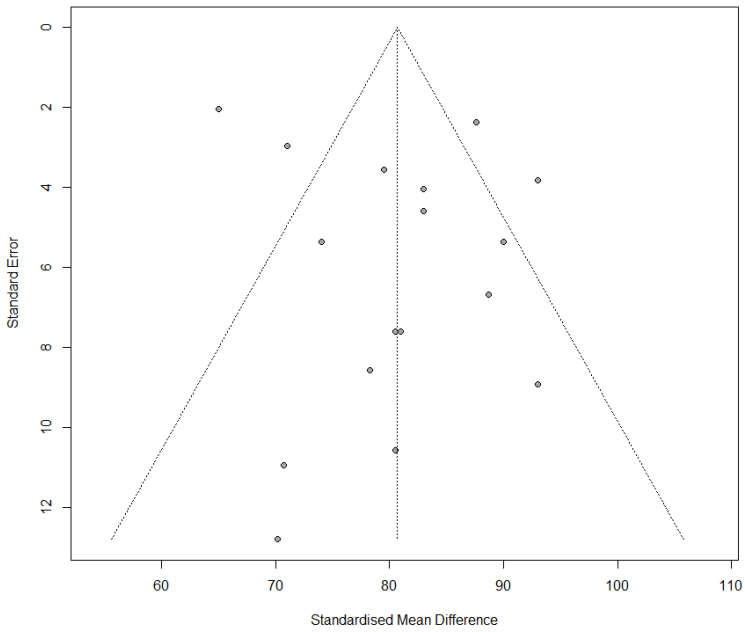
Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics

Figure S 3. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related healthcare utilisation, including primary care visits, emergency department visits, hospital admissions and intensive care unit admissions in the included studies with low-risk of bias



Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics

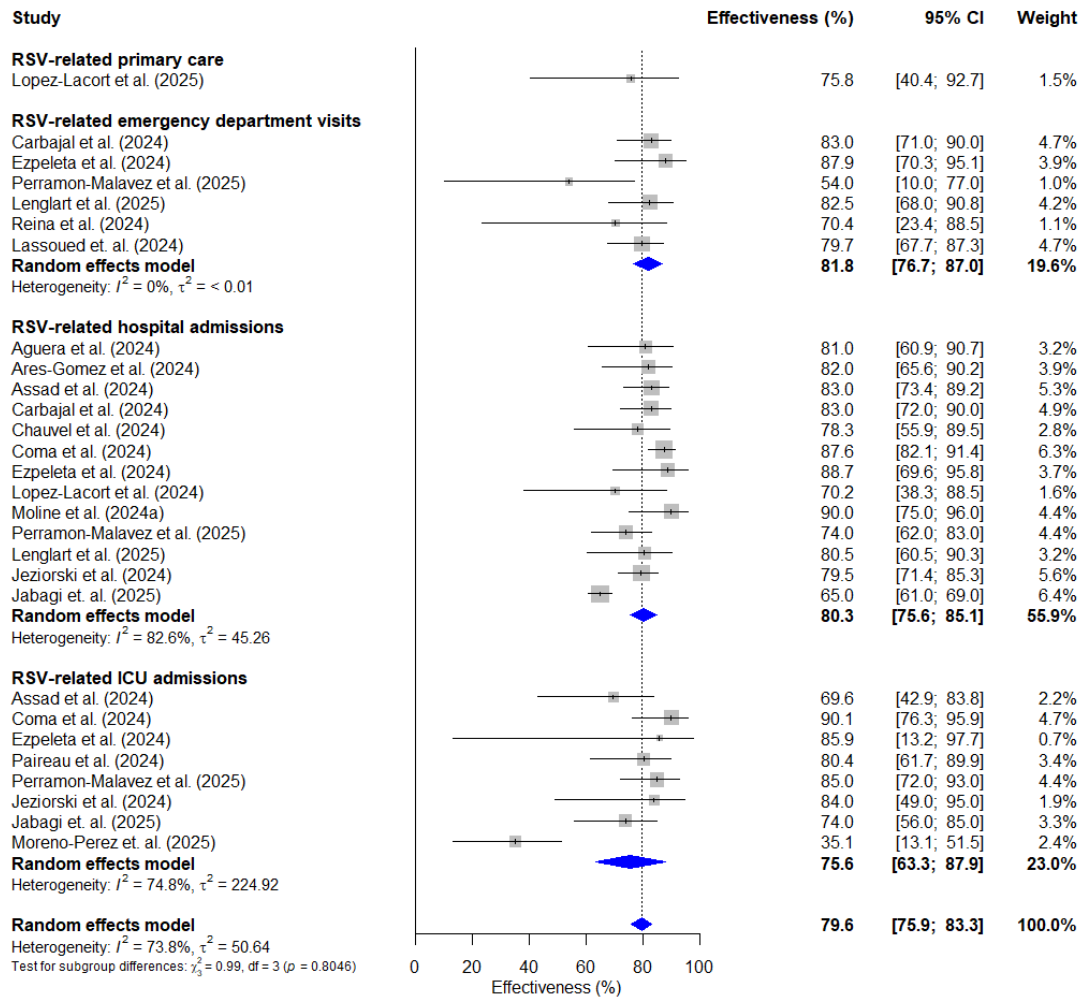
Figure S 4. Funnel plot and Egger's test in meta-analysis for the effectiveness of Nirsevimab against Respiratory Syncytial Virus (RSV)-related hospital admissions (n=17)



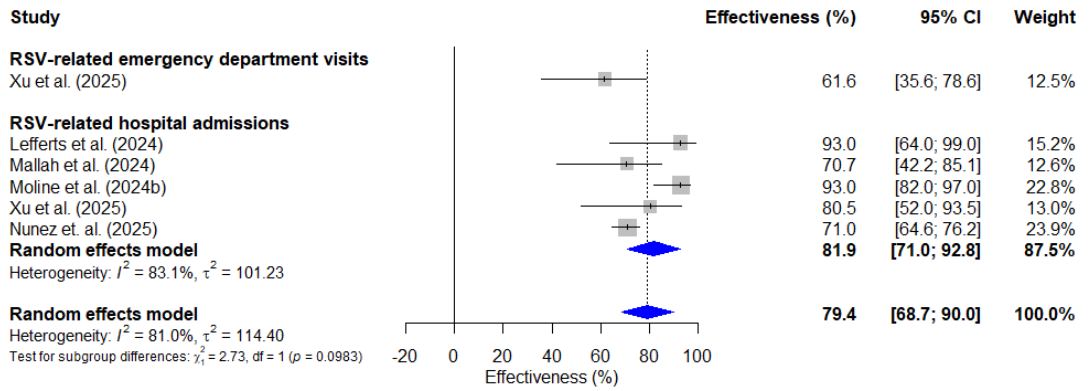
Egger's test: p-value= 0.2453

Figure S 5. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related healthcare utilisation, including primary care visits, emergency department visits, hospital admissions and intensive care unit admissions by the length of follow-up

(a) Length of follow-up ≤5 months



(b) Length of follow-up >5 months



Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics

Figure S 6. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related hospital admission by sex assigned at birth

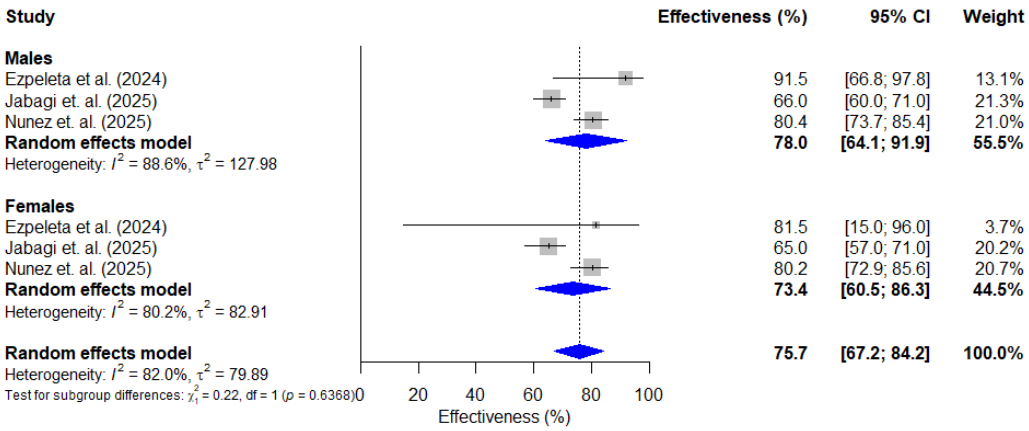
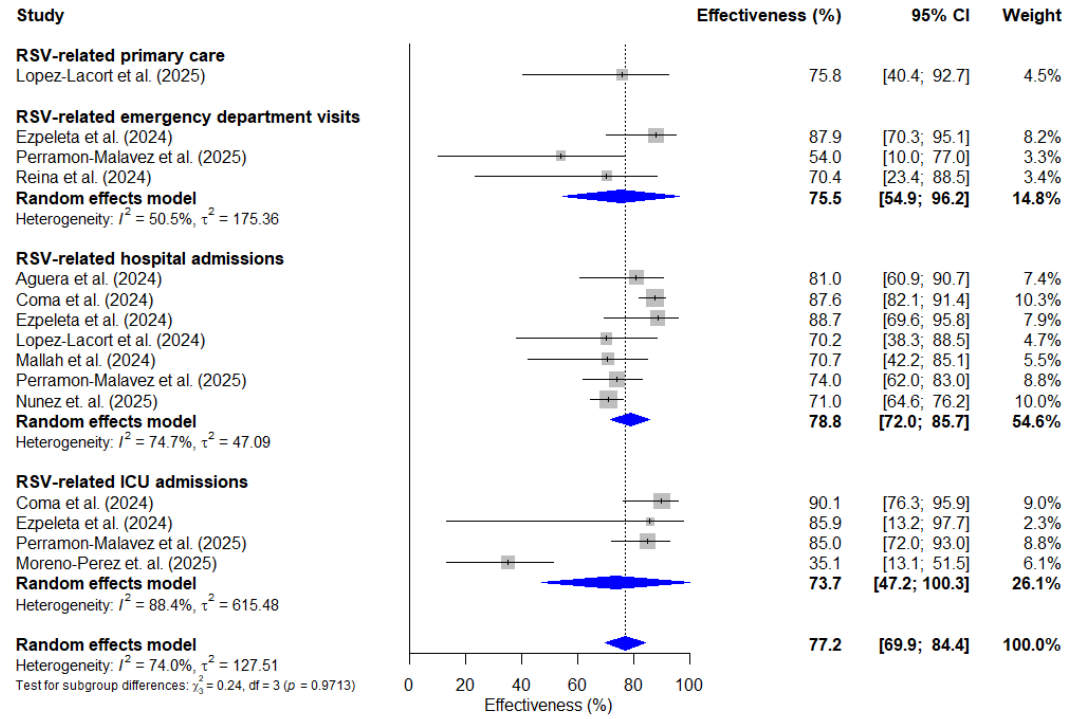
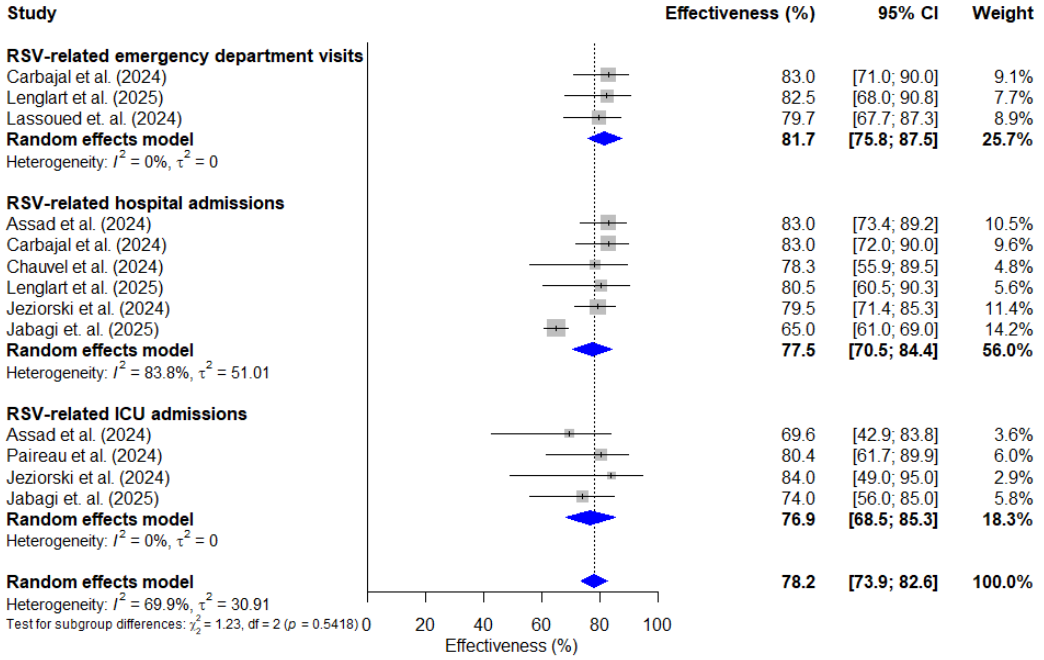


Figure S 7. Effectiveness of nirsevimab in infants against Respiratory Syncytial Virus (RSV)-related healthcare utilisation, including primary care visits, emergency department visits, hospital admissions and intensive care unit admissions by country

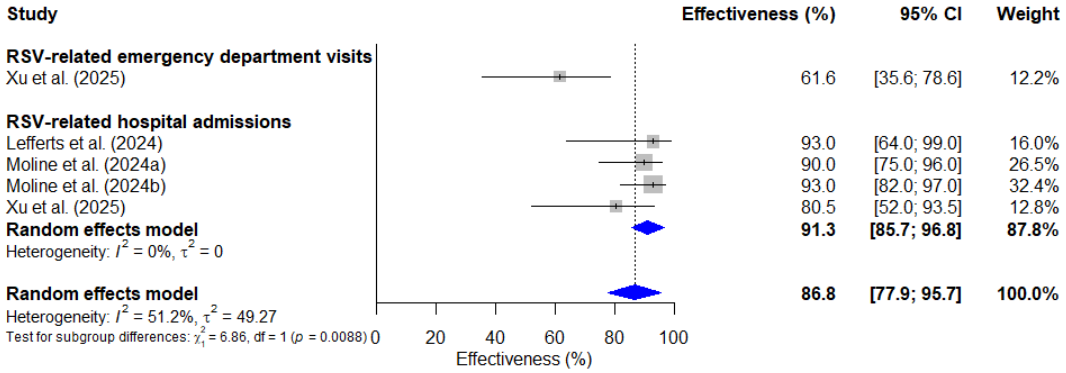
(a) Spain



(b) France



(c) USA



Note: emergency department visits included data from emergency department, ambulatory care and/or outpatient clinics

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