

S6. RECURRENT ACUTE OTITIS MEDIA

GRADE EVIDENCE PROFILE

In children with RAOM, is the use of antibiotic prophylaxis effective in reducing the recurrence of episodes?

Patient or population: child with RAOM

Setting: Outpatient

Intervention: antibiotic prophylaxis with penicillins

Comparison: Compared to no prophylaxis

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	[Profilassi antibiotica - penicilline]	[nessuna profilassi]	Relative (95% CI)	Absolute (95% CI)		

Table S6.1. Reduction in the number of AOMs (follow-up: range 3 months to 12 months; assessed with: AOM incidence in the follow-up period)

2 ^{1,2}	randomised trials	serious ^{a,b}	not serious	not serious	not serious	publication bias strongly suspected ^{c,d}	20/55 (36.4%)	53/61 (86.9%)	RR 0.38 (0.16 to 0.90)	539 fewer per 1.000 (from 730 fewer to 87 fewer)	⊕⊕○○ Low	CRITIC
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Table S6.2. Reduction in the number of AOM - prophylaxis with penicillin V in doses of 25 mg/kg/day (follow-up: range 3 months to 15 months; assessed with: number of children without any improvement, either total or partial (max 1 AOM in 3 months))

In children with RAOM, is the use of antibiotic prophylaxis effective in reducing the recurrence of episodes?

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Comparison: Compared to no prophylaxis

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	[Profilassi antibiotica - penicilline]	[nessuna profilassi]	Relative (95% CI)	Absolute (95% CI)		
1 ³	randomised trials	serious ^{a,b}	not serious	not serious	not serious	all plausible residual confounding would reduce the demonstrated effect ^c	22/60 (36.7%)	29/48 (60.4%)	RR 0.61 (0.41 to 0.91)	236 fewer per 1.000 (from 356 fewer to 54 fewer)	⊕⊕⊕⊕ High	CRITIC

CI: confidence interval; **RR:** risk ratio

Explanations

a. Randomization: Unclear risk of bias

b. Allocation concealment: high risk of bias

c. clinically insignificant results: average <1 AOM/pc in the follow-up period

d. Low sample size

e. Correlation between therapeutic success and breast milk intake in both groups

References

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In children with RAOM, is the use of antibiotic prophylaxis effective in reducing the recurrence of episodes?

Patient or population: child with RAOM

Setting: Outpatient

Intervention: antibiotic prophylaxis with sulfonamides or macrolides

Comparison: Compared to no prophylaxis

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	[Profilassi antibiotica - Sulfamidici]	[nessuna profilassi]	Relative (95% CI)	Absolute (95% CI)		

Table S6.3. Reduction in the number of AOMs - TMP-SMZ prophylaxis (follow-up: range 3 months to 6 months; assessed with: AOM incidence in the follow-up period)

4 ^{1,2,3,4}	randomised trials	serious ^{a, b}	not serious	not serious	not serious	publication bias strongly suspected ^c	31/84 (36.9%)	66/84 (78.6%)	RR 0.47 (0.35 to 0.63)	416 fewer per 1.000 (from 511 fewer to 291 fewer)	⊕⊕○○ Low	CRITIC
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Table S6.4. Reduction number of AOM - Sulfonamides (follow-up: range 3 months to 24 months; assessed with: No. of AOM/patient in the follow-up period - Average (DS))

In children with RAOM, is the use of antibiotic prophylaxis effective in reducing the recurrence of episodes?

Patient or population: child with RAOM

Setting: Outpatient

Intervention: antibiotic prophylaxis with sulfonamides or macrolides

Comparison: Compared to no prophylaxis

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	[Profilassi antibiotica - Sulfamidici]	[nessuna profilassi]	Relative (95% CI)	Absolute (95% CI)		
3 ^{2,5,6}	randomised trials	serious ^d	not serious	not serious	not serious	publication bias strongly suspected ^d	92	93	-	MD 1.18 fewer (4.07 fewer to 1.72 more)	⊕⊕○○ Low	CRITIC

Table S6.5. Reduction in AOM number - Sulfisoxazole - NRCT (follow-up: mean 72 months; assessed with: incidence of AOM/year/group)

1 ⁷	non-randomised studies ^e	serious ^{e,f}	not serious	not serious	not serious	publication bias strongly suspected all plausible residual confounding would reduce the	3/26 (11.5%)	11/26 (42.3%)	RR 0.27 (0.09 to 0.87)	309 fewer per 1.000 (from 385 fewer to 55 fewer)	⊕⊕⊕○ Moderate	CRITIC
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Setting: Outpatient

Intervention: antibiotic prophylaxis with sulfonamides or macrolides

Comparison: Compared to no prophylaxis

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	[Profilassi antibiotica - Sulfamidici]	[nessuna profilassi]	Relative (95% CI)	Absolute (95% CI)		
						demonstrated effect ^g		42.3%		309 fewer per 1.000 (from 385 fewer to 55 fewer)		

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

- a. Randomizzazione: UNCLEAR rischio di bias in 3 su 4 RCT
- b. Allocation concealment: alto rischio di bias in 3 su 4 RCT
- c. risultati clinicamente non rilevanti: mediamente meno di 1 AOM/pz in 3-6 mesi anche nel gruppo controllo
- d. risultati discordanti rispetto agli studi che valutano l'incidenza. 2 su 3 RCT di migliore qualità metodologica non riportano differenze statisticamente significative
- e. Studio di intervento controllato non randomizzato
- f. mancanza di cecità

g. risultati per paziente clinicamente non rilevanti sia nel gruppo intervento che nel gruppo controllo: rispettivamente 0,1/pz/anno e 0.4/pz/anno

References

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