IQWiG

Drug assessment at a glance: A26-16[1]

Colchicine (prophylaxis of ischaemic cardiovascular events after myocardial infarction)

31 August 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-16. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Prophylaxis of ischaemic cardiovascular events in adult patients with atherosclerotic coronary artery disease and a recent myocardial infarction
Intervention	colchicine; in addition to optimized standard therapy
Comparator	Optimized standard therapy for the secondary prevention of ischaemic cardiovascular events in patients with atherosclerotic coronary artery disease and a recent myocardial infarction, as well as for the treatment of any existing accompanying diseases, such as, for example, hypertension, cardiac failure, diabetes mellitus and concomitant symptoms
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	↔	★
Morbidity	↔ (serious cardiovascular events) ↑ (stroke)	★
Symptoms	ø	–
Health-related quality of life	ø	–
Side effects	↔	★

ø	No (suitable) data	–	Not applicable
↔	No advantage or disadvantage	★	Low
↑ / ↓	Small advantage/disadvantage	★★	Moderate
↑↑ / ↓↓	Moderate advantage/disadvantage	★★★	High
↑↑↑ / ↓↓↓	Large advantage/disadvantage		

Overall: an advantage of unclear magnitude with low informative value

Evidence base and noteworthy aspects

- Evidence base: COLCOT study (double-blind RCT: colchicine + optimized standard therapy [N = 2366] versus placebo + optimized standard therapy [N = 2379])

- The standard therapies used largely represent the guideline recommendations for the secondary prevention of ischaemic cardiovascular events in patients with atherosclerotic coronary artery disease and a recent myocardial infarction, as well as for the treatment of any existing accompanying diseases. However, not all patients with type 2 diabetes mellitus received treatment in accordance with the guidelines. Furthermore, some data on laboratory values, such as LDL-C levels and blood pressure, were missing for the assessment of the concomitant treatment. The certainty of conclusions regarding the results of the COLCOT study was therefore limited.
- The primary composite outcome was deemed unsuitable. For the secondary composite outcome relevant to the assessment – serious cardiovascular events, comprising cardiovascular death, stroke (nonfatal), resuscitated cardiac arrest (nonfatal) and acute myocardial infarction (nonfatal) – no advantage or disadvantage was shown for treatment with colchicine. However, there was a moderate advantage for nonfatal strokes, which was also confirmed by analyses that additionally took nonfatal strokes into account. As an advantage was shown in only one component of the

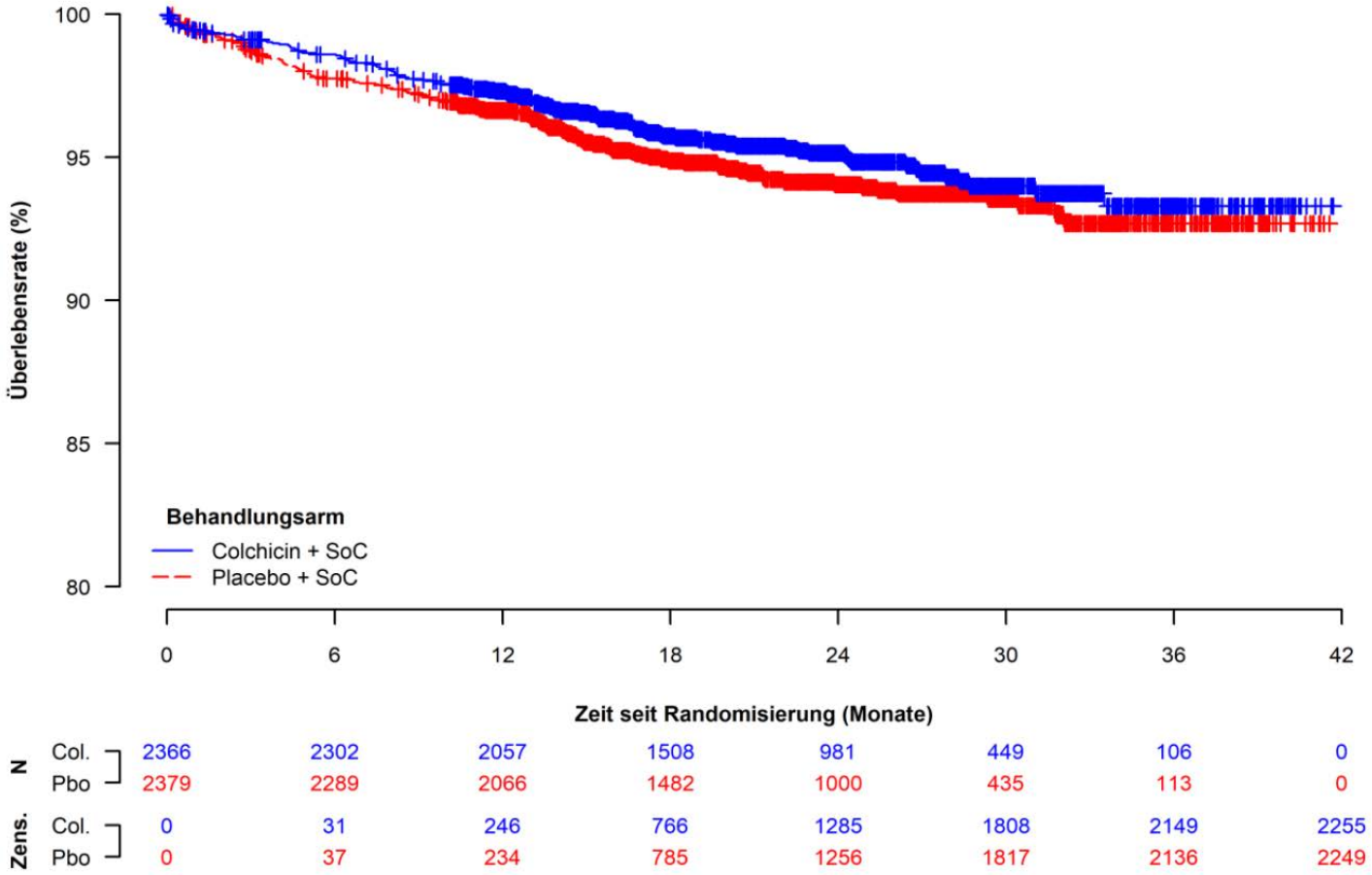
composite outcome, and only few nonfatal or fatal strokes occurred, the overall magnitude of the advantage was unclear.

Key study findings

Study Outcome category Outcome	colchicine + optimized standard therapy		placebo + optimized standard therapy		colchicine + optimized standard therapy vs. placebo + optimized standard therapy
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI]; p-value
COLCOT					
Mortality					
All-cause mortality	2366	NA 43 (1.8)	2379	NA 44 (1.8)	0.98 [0.64; 1.49]; 0.930
Morbidity					
Serious cardiovascular events	2366	NA 111 (4.7)	2379	NA 130 (5.5)	0.85 [0.66; 1.10]; 0.219
Cardiovascular death	2366	NA 20 (0.8)	2379	NA 24 (1.0)	0.84 [0.46; 1.52]; 0.560
Stroke (nonfatal)	2366	NA 5 (0.2)	2379	NA 19 (0.8)	0.26 [0.10; 0.70]; 0.004
Resuscitated cardiac arrest (nonfatal)	2366	NA 5 (0.2)	2379	NA 6 (0.3)	0.83 [0.25; 2.73]; 0.762
Acute myocardial infarction (nonfatal)	2366	NA 89 (3.8)	2379	NA 98 (4.1)	0.91 [0.68; 1.21]; 0.521

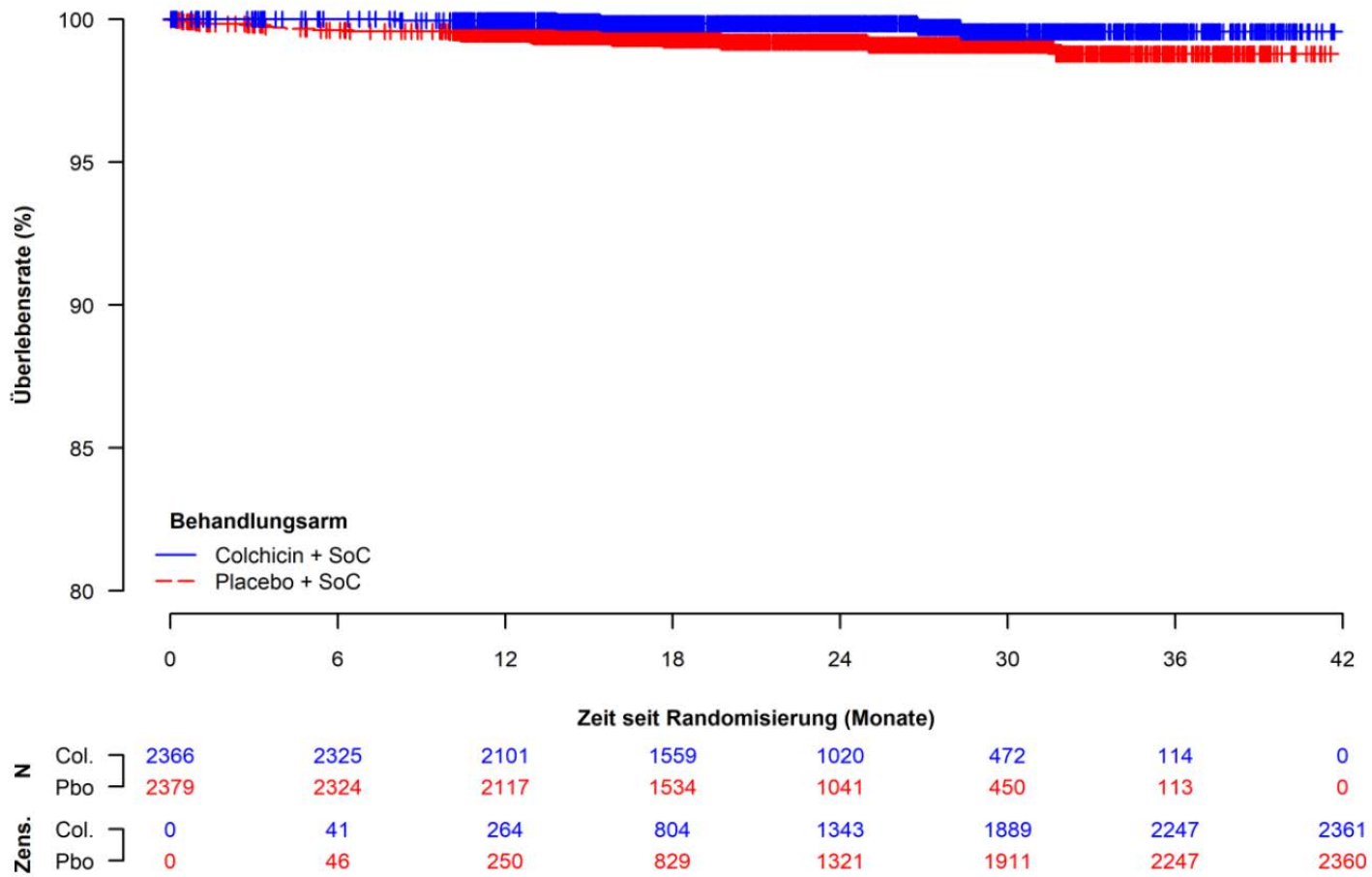
Study Outcome category Outcome	colchicine + optimized standard therapy		placebo + optimized standard therapy		colchicine + optimized standard therapy vs. placebo + optimized standard therapy
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p-value
COLCOT					
Side effects					
SAEs	2330	259 (11.1)	2346	268 (11.4)	0.97 [0.83, 1.14]; 0.805
Discontinuation due to AEs	No suitable data				

Kaplan-Meier curves on serious cardiovascular events



Behandlungsarm: Treatment arm; Überlebensrate: Survival rate; Zeit seit Randomisierung (Monate): Time since randomization (months); Zens.: Cens.

Kaplan-Meier curves on stroke



Behandlungsarm: Treatment arm; Überlebensrate: Survival rate; Zeit seit Randomisierung (Monate): Time since randomization (months); Zens.: Cens.

References

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-16.html and https://www.iqwig.de/en/projects/a26-82.html.

Publisher details

Publisher

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