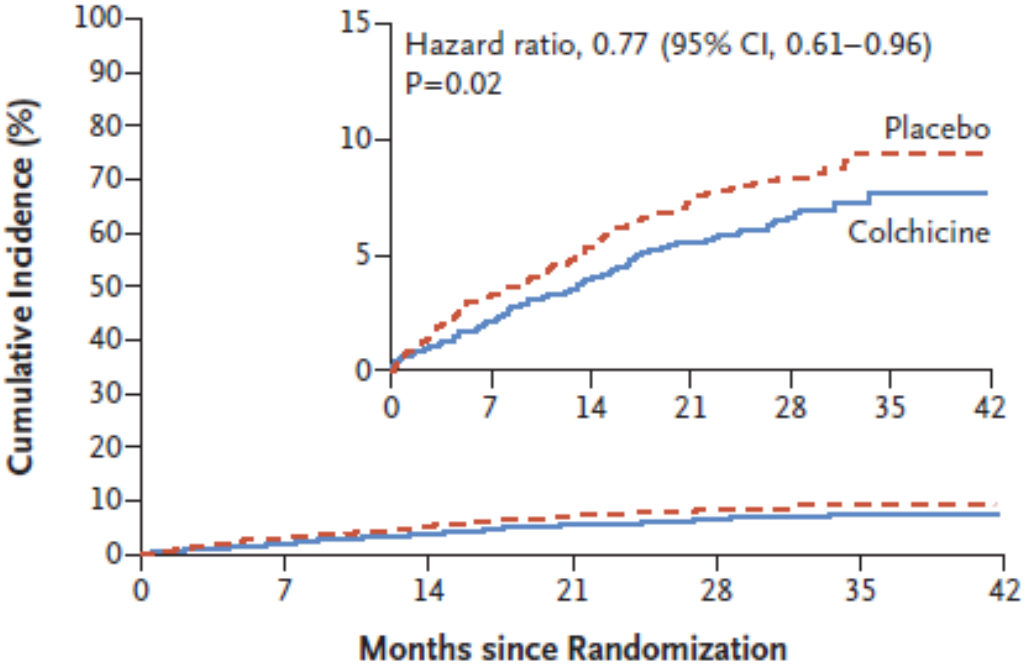
Table 2. 主要転帰

転帰	コルヒチン (N=2366)	プラセボ (N=2379)	危険率 (95% CI)	P Value
	数（パーセント）			
主要転帰全体	131 (5.5)	170 (7.1)	0.77 (0.61–0.96)	0.02†
転帰の内容				
心血管疾患による死亡	20 (0.8)	24 (1.0)	0.84 (0.46–1.52)	
蘇生された心停止	5 (0.2)	6 (0.3)	0.83 (0.25–2.73)	
心筋梗塞	89 (3.8)	98 (4.1)	0.91 (0.68–1.21)	
脳卒中	5 (0.2)	19 (0.8)	0.26 (0.10–0.70)	
狭心症による救急入院-PTC等による	25 (1.1)	50 (2.1)	0.50 (0.31–0.81)	
二次転帰	111 (4.7)	130 (5.5)	0.85 (0.66–1.10)	
死亡	43 (1.8)	44 (1.8)	0.98 (0.64–1.49)	
深部静脈血栓症又は肺血栓	10 (0.4)	7 (0.3)	1.43 (0.54–3.75)	
心房細動	36 (1.5)	40 (1.7)	0.93 (0.59–1.46)	

* Only the initial event was counted in the analyses of time to first event for the primary composite end point and for the secondary composite end point. In the component analysis, the different types of events were counted separately.
† The log-rank test and the multivariable Cox proportional-hazards model including age, history of diabetes, previous coronary revascularization, and previous heart failure yielded similar P values.
‡ The secondary composite end point included death from cardiovascular causes, resuscitated cardiac arrest, myocardial infarction, and stroke.



No. at Risk							
Placebo	2379	2261	1854	1224	622	144	0
Colchicine	2366	2284	1868	1230	628	153	0

Figure 2. Cumulative Incidence of Cardiovascular Events (Intention-to-Treat Population).

Shown are the Kaplan–Meier event curves for the primary efficacy composite end point of death from cardiovascular causes, resuscitated cardiac arrest, myocardial infarction, stroke, or urgent hospitalization for angina leading to coronary revascularization in the colchicine group and the placebo group in a time-to-event analysis. The inset shows the same data on an enlarged y axis.

Table 1. Characteristics of the Patients.*

Characteristic	Colchicine (N=2366)	Placebo (N=2379)
Age — yr	60.6±10.7	60.5±10.6
Female sex — no. (%)	472 (19.9)	437 (18.4)
White race — no./total no. (%)†	1350/1850 (73.0)	1329/1844 (72.1)
Body-mass index	28.2±4.8	28.4±4.7
Current smoking — no./total no. (%)	708/2366 (29.9)	708/2377 (29.8)
Hypertension — no. (%)	1185 (50.1)	1236 (52.0)
Diabetes — no. (%)	462 (19.5)	497 (20.9)
History of myocardial infarction — no. (%)	370 (15.6)	397 (16.7)
History of PCI — no. (%)	392 (16.6)	406 (17.1)
History of CABG — no. (%)	69 (2.9)	81 (3.4)
History of heart failure — no. (%)	48 (2.0)	42 (1.8)
History of stroke or TIA — no. (%)	55 (2.3)	67 (2.8)
Time from index myocardial infarction to randomization — days	13.4±10.2	13.5±10.1
PCI for index myocardial infarction — no./total no. (%)	2192/2364 (92.7)	2216/2375 (93.3)
Medication use — no. (%)		
Aspirin	2334 (98.6)	2352 (98.9)
Other antiplatelet agent	2310 (97.6)	2337 (98.2)
Statin	2339 (98.9)	2357 (99.1)
Beta-blocker	2116 (89.4)	2101 (88.3)

* Plus–minus values are means ±SD. Data were missing on the following characteristics: age (assessed according to date of birth; see below) for 435 patients (215 in the colchicine group and 220 in the placebo group), body-mass index (the weight in kilograms divided by the square of the height in meters) for 5 (1 and 4 patients, respectively), and information about the index myocardial infarction for 6 (2 and 4 patients, respectively). Date of birth and race were not required fields because both were considered in some countries to be sensitive data that could allow for the identification of patients. For statistical reporting, missing information regarding the day of birth was replaced by 15, and missing information regarding the month and day of birth was replaced by July 1. CABG denotes coronary-artery bypass graft surgery, PCI percutaneous coronary intervention, and TIA transient ischemic attack.

† Race was reported by the patient.

Table 3. Adverse Events (Safety Population).*

Event	Colchicine (N=2330)	Placebo (N=2346)	P Value
	number of patients (percent)		
Any related adverse event†	372 (16.0)	371 (15.8)	0.89
Adverse events			
Gastrointestinal event	408 (17.5)	414 (17.6)	0.90
Diarrhea	225 (9.7)	208 (8.9)	0.35
Nausea	43 (1.8)	24 (1.0)	0.02
Flatulence	15 (0.6)	5 (0.2)	0.02
Gastrointestinal hemorrhage	7 (0.3)	5 (0.2)	0.56
Anemia	14 (0.6)	10 (0.4)	0.40
Leukopenia	2 (0.1)	3 (0.1)	0.66
Thrombocytopenia	3 (0.1)	7 (0.3)	0.21
Serious adverse events			
Any serious adverse event‡	383 (16.4)	404 (17.2)	0.47
Gastrointestinal event	46 (2.0)	36 (1.5)	0.25
Infection	51 (2.2)	38 (1.6)	0.15
Pneumonia	21 (0.9)	9 (0.4)	0.03
Septic shock	2 (0.1)	2 (0.1)	0.99
Hospitalization for heart failure	25 (1.1)	17 (0.7)	0.21
Cancer§	43 (1.8)	46 (2.0)	0.77

Table S6. Biomarkers of Inflammation.

Biomarker	Colchicine	Placebo
Hs-C reactive protein (mg/L)	N=99	N=108
Randomization, geometric mean (IQR)†	4.27 (2.12, 7.22)	5.09 (2.45, 11.96)
6 months, geometric mean (IQR)	1.37 (0.75, 2.13)	1.60 (0.90, 2.65)
Adjusted GM percent change (95% CI)‡	-70.0 (-74.6, -64.5)	-66.6 (-71.5, -60.8)
Placebo-adjusted GM percent change (95% CI)¶	-10.1 (-28.6, 13.4)	- -
Total white blood cell count ($10^3/\mu L$)	N=992	N=980
Randomization, geometric mean (IQR)†	8.54 (7.10, 10.40)	8.63 (7.20, 10.70)
12 months, geometric mean (IQR)	6.95 (5.99, 8.30)	7.03 (5.96, 8.48)
Adjusted GM percent change (95% CI)‡	-18.81 (-20.12, -17.47)	-19.02 (-20.46, -17.55)
Placebo-adjusted GM percent change (95% CI)¶	0.26 (-2.15, 2.72)	- -
Circulating lymphocytes ($10^3/\mu L$)		
Randomization, geometric mean (IQR)†	1.79 (1.40, 2.40)	1.79 (1.42, 2.46)
12 months, geometric mean (IQR)	1.83 (1.50, 2.44)	1.82 (1.50, 2.44)
Adjusted GM percent change (95% CI)‡	1.80 (-0.46, 4.11)	0.69 (-1.54, 2.98)
Placebo-adjusted GM percent change (95% CI)¶	1.10 (-2.06, 4.36)	- -
Circulating neutrophils ($10^3/\mu L$)		
Randomization, geometric mean (IQR)†	5.45 (4.36, 7.15)	5.47 (4.30, 7.46)
12 months, geometric mean (IQR)	3.95 (3.27, 5.08)	3.99 (3.34, 5.20)
Adjusted GM percent change (95% CI)‡	-27.63 (-29.48, -25.73)	-27.95 (-29.91, -25.93)
Placebo-adjusted GM percent change (95% CI)¶	0.45 (-3.28, 4.32)	- -

GM denotes geometric mean, HS high-sensitivity, and IQR inter-quartile range.

†The geometric mean was obtained by exponentiating the mean of log-transformed data.

‡ The adjusted geometric mean percent change was obtained by exponentiating the adjusted mean from the analysis of covariance model (based on log-transformed data), then subtracting 1 and multiplying by 100. The bounds of the 95% confidence intervals were obtained similarly.