End-of-trial inflammatory biomarkers, lipid levels, creatine kinase and markers of renal and liver function in the LoDoCo2 trial


1Radboud University Medical Center, Cardiology, Nijmegen, The Netherlands; 2University Medical Center Utrecht, Cardiology, Utrecht, The Netherlands; 3Meander Medical Center, Cardiology, Amersfoort, The Netherlands; 4McMaster University, Medicine, Hamilton, Canada; 5Heart and Vascular Research Institute of Western Australia, Perth, Australia; 6Northwest Clinics, Internal Medicine, Alkmaar, The Netherlands; 7Amsterdam UMC, Cardiology, Amsterdam, The Netherlands; 8University Medical Center Utrecht, Vascular Surgery, Utrecht, The Netherlands; 9University of Western Australia, School of Population and Global Health, Perth, Australia

On behalf of LoDoCo2 Steering Committee

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Background: The Low-Dose Colchicine 2 (LoDoCo2) trial demonstrated that colchicine reduced major cardiovascular events in patients with chronic coronary artery disease (CAD). The effect of long-term colchicine treatment on inflammatory biomarkers and markers reflecting renal and liver function have not been investigated yet.

Purpose: This substudy examines levels of inflammatory biomarkers, lipid fractions, creatine kinase (CK) and markers of renal and liver function at close-out of the trial.

Methods: The LoDoCo2 trial randomly assigned patients with chronic CAD to colchicine 0.5 mg once daily or placebo. Blood samples were drawn during close-out visits after a median follow-up of 32.7 (interquartile range [IQR] 24.0–48.6) months.

Results: Assignment to colchicine was associated with lower levels of high-sensitivity C-Reactive Protein (0.94 mg/L [0.53–1.93] vs. 1.24 mg/L [0.73–2.55]; −24.2%; p < 0.01) and interleukin-6 (2.70 ng/L [1.79–4.18] vs. 3.16 ng/L [2.07–4.95]; −14.9%; p < 0.01), but was not associated with any differences in lipid fractions or markers of renal function. Although CK levels were higher after colchicine (123.0 U/L, [84.0–184.0] vs. 110.0 U/L, [77.0–164.0]; p < 0.01), the number of participants with marked elevations of CK (>5 times upper limit of normal [ULN]) was low and not different between treatment groups. Levels of alanine aminotransferase (ULN 40 U/L) and albumin (ULN 50 U/L) were higher (p < 0.01) in the colchicine group compared to placebo (30.0 U/L [22.0–40.0] vs. 26.0 U/L [19.0–34.0] and 43.01 g/L±2.39 vs. 42.64 g/L±2.48, respectively). There were no differences in gamma-glutamyl transferase or bilirubin.

Conclusion: Long-term low-dose colchicine in patients with chronic CAD was associated with lower levels of hs-CRP and IL-6 but was not associated with clinically important differences in lipid fractions, CK, renal or liver function.