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Blood-Pressure and Cholesterol Lowering in Persons without Cardiovascular Disease

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NEW ENGLAND JOURNAL OF MEDICINE
Volume: 374 Issue: 21 Pages: 2032-2043
DOI: 10.1056/NEJMoa1600177
Published: MAY 26 2016
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Abstract
BACKGROUND

Elevated blood pressure and elevated low-density lipoprotein (LDL) cholesterol increase the risk of cardiovascular disease. Lowering both should reduce the risk of cardiovascular events substantially.

METHODS

In a trial with 2-by-2 factorial design, we randomly assigned 12,705 participants at intermediate risk who did not have cardiovascular disease to rosuvastatin (10 mg per day) or placebo and to candesartan (16 mg per day) plus hydrochlorothiazide (12.5 mg per day) or placebo. In the analyses reported here, we compared the 3180 participants assigned to combined therapy (with rosuvastatin and the two antihypertensive agents) with the 3168 participants assigned to dual placebo. The first primary outcome was the composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke, and the second coprimary outcome additionally included heart failure, cardiac arrest, or revascularization. The median follow-up was 5.6 years.

RESULTS

The decrease in the LDL cholesterol level was 33.7 mg per deciliter (0.87 mmol per liter) greater in the combined-therapy group than in the dual-placebo group, and the decrease in systolic blood pressure was 6.2 mm Hg greater with combined therapy than with dual placebo. The first coprimary outcome occurred in 113 participants (3.6%) in the combined-therapy group and in 157 (5.0%) in the dual-placebo group (hazard ratio, 0.71; 95% confidence interval [CI], 0.56 to 0.90; P=0.005). The second coprimary outcome occurred in 136 participants (4.3%) and 187 participants (5.9%), respectively (hazard ratio, 0.72; 95% CI, 0.57 to 0.89; P=0.003). Muscle weakness and dizziness were more common in the combined-therapy group than in the dual-placebo group, but the overall rate of discontinuation of the trial regimen was similar in the two groups.

CONCLUSIONS

The combination of rosuvastatin (10 mg per day), candesartan (16 mg per day), and hydrochlorothiazide (12.5 mg per day) was associated with a significantly lower rate of cardiovascular events than dual placebo among persons at intermediate risk who did not have cardiovascular disease. (Funded by the Canadian Institutes of Health Research and AstraZeneca; ClinicalTrials.gov number, NCT00468923.)

Keywords
Keywords Plus: RISK-FACTORS; TRIAL; PREVENTION; MORTALITY; METAANALYSIS; INTERHEART; COUNTRIES; STRATEGY; STROKE; ADULTS

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Funding

Funding Agency	Grant Number
Canadian Institutes of Health Research	
AstraZeneca	

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Publisher

MASSACHUSETTS MEDICAL SOC, WALTHAM WOODS CENTER, 860 WINTER ST., WALTHAM, MA 02451-1413 USA

Categories / Classification

Research Areas: General & Internal Medicine

Web of Science Categories: Medicine, General & Internal

Document Information

Document Type: Article

Language: English

Accession Number: WOS:000376443500006

PubMed ID: 27039945

ISSN: 0028-4793

eISSN: 1533-4406

Journal Information

Impact Factor: Journal Citation Reports®

Other Information

ID# Number: DMEEN

Cited References in Web of Science Core Collection: 21

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New England Journal of Medicine
Volume 374, Issue 21, 26 May 2016, Pages 2032-2043

Blood-pressure and cholesterol lowering in persons without cardiovascular disease (Article)

Yusuf, S.^{1,2}, Lonn, E.³, Pais, P.³, Bosch, J.², López-Jaramillo, P.¹, Zhu, J.³, Xavier, D.³, Avezum, A.¹, Leiter, L.A.¹, Piegas, L.S.³, Parkhomenko, A.², Kelai, M.³, Kelai, K.³, Sliwa, K.³, Chazova, I.², Peters, R.J.G.¹, Held, C.³, Yusuf, K.³, Lewis, B.S.³, Jansky, P.³, Khunti, K.³, Toff, W.D.³, Reid, C.M.^{3,4,5}, Vargos, J.³, Aconi, J.L.³, McKelvie, R.³, Pogue, J.³, Jung, H.³, Liu, L.³, Diaz, R.³, Dams, A.³, Dagenais, G.¹

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Abstract

BACKGROUND Elevated blood pressure and elevated low-density lipoprotein (LDL) cholesterol increase the risk of cardiovascular disease. Lowering both should reduce the risk of cardiovascular events substantially. **METHODS** In a trial with 2-by-2 factorial design, we randomly assigned 12,705 participants at intermediate risk who did not have cardiovascular disease to rosuvastatin (10 mg per day) or placebo and to candesartan (16 mg per day) plus hydrochlorothiazide (12.5 mg per day) or placebo. In the analyses reported here, we compared the 3180 participants assigned to combined therapy (with rosuvastatin and the two antihypertensive agents) with the 3168 participants assigned to dual placebo. The first coprimary outcome was the composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke, and the second coprimary outcome additionally included heart failure, cardiac arrest, or revascularization. The median follow-up was 5.6 years. **RESULTS** The decrease in the LDL cholesterol level was 33.7 mg per deciliter (0.87 mmol per liter) greater in the combined-therapy group than in the dual-placebo group, and the decrease in systolic blood pressure was 6.2 mm Hg greater with combined therapy than with dual placebo. The first coprimary outcome occurred in 113 participants (3.6%) in the combined-therapy group and in 157 (5.0%) in the dual-placebo group (hazard ratio, 0.71; 95% confidence interval [CI], 0.56 to 0.90; P = 0.005). The second coprimary outcome occurred in 136 participants (4.3%) and 187 participants (5.9%), respectively (hazard ratio, 0.72; 95% CI, 0.57 to 0.89; P = 0.003). Muscle weakness and dizziness were more common in the combined-therapy group than in the dual-placebo group, but the overall rate of discontinuation of the trial regimen was similar in the two groups. **CONCLUSIONS** The combination of rosuvastatin (10 mg per day), candesartan (16 mg per day), and hydrochlorothiazide (12.5 mg per day) was associated with a significantly lower rate of cardiovascular events than dual placebo among persons at intermediate risk who did not have cardiovascular disease. Copyright © 2016 Massachusetts Medical Society. All rights reserved.

Indexed keywords

EMTREE drug terms: antihypertensive agent; candesartan; hydrochlorothiazide; low density lipoprotein cholesterol; placebo; rosuvastatin; antihypertensive agent; benzimidazole derivative; candesartan; hydrochlorothiazide; hydroxymethylglutaryl coenzyme A reductase inhibitor; low density lipoprotein cholesterol; rosuvastatin; tetrazole derivative
EMTREE medical terms: adult; Article; blood pressure measurement; cardiovascular disease; cardiovascular risk; cerebrovascular accident; cholesterol blood level; controlled study; dizziness; double blind procedure; factorial design; female; heart arrest; heart failure; heart infarction; human; hypotension; major clinical study; middle aged; multicenter study; muscle weakness; myalgia; priority journal; randomized controlled trial; revascularization; risk factor; risk reduction; aged; blood; Cardiovascular Diseases; clinical trial; combination drug therapy; comparative study; hypertension; male; medication compliance

MeSH: Aged; Antihypertensive Agents; Benzimidazoles; Cardiovascular Diseases; Cholesterol; LDL; Double-Blind Method; Drug Therapy; Combination; Female; Humans; Hydrochlorothiazide; Hydroxymethylglutaryl-CoA Reductase Inhibitors; Hypertension; Male; Medication Adherence; Middle Aged; Risk Factors; Rosuvastatin Calcium; Tetrazoles
Medline is the source for the MeSH terms of this document.

Chemicals and CAS Registry Numbers: candesartan, 130461-59-7; hydrochlorothiazide, 58-93-5; rosuvastatin, 147068-18-8, 147068-20-2; Antihypertensive Agents; Benzimidazoles; candesartan; Cholesterol; LDL; Hydrochlorothiazide; Hydroxymethylglutaryl-CoA Reductase Inhibitors; Rosuvastatin Calcium; Tetrazoles

ISSN: 0028-4793 CODEN: NEJM Source Type: Journal Original language: English
DOI: 10.1056/NEJMoa1601177 PubMed ID: 27039945 Document Type: Article
Publisher: Massachusetts Medical Society

Funding details

Funding number	Funding sponsor	Acronym
	AstraZeneca	

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