

Acute and Sustained Effects of Plant-based Bioequivalent Inorganic Nitrate Supplement Tablets on Blood Pressure Reduction in Pre-hypertensives Men and Women



Lavanya Cherukuri, MD.; Chandana Shekar, MD.; Dong Li, PhD.; Divya Birudaraju, MD.; Sajad Hamal, MS.; Ferdinand Flores, BSN.; Sion Roy, MD.; William Sotka, MA.; Shawn J. Green, PhD.; Matthew Budoff, MD.

Los Angeles Institute of Biomedical Research at Harbor UCLA Medical Center, Torrance, CA



INTRODUCTION

➤ This study assessed the efficacy of inorganic nitrate-containing tablets (NO₃) {Berkeley Life} to elevate nitric oxide (NO) bioavailability as determined by saliva conversion of NO₃ to nitrite, a required step to produce NO, in relationship to lowering blood pressure (BP) in men and women with pre-hypertension.

METHODS

- 67 individuals with mean baseline systolic and diastolic BP >142 and 80 mmHg were randomized to receive daily, single dosing of 314 mg NO₃ or NO₃-free (placebo) tablets in a double-blinded study for 12 weeks.
- 26 men and 41 women; age of 59.3 ± 9.0 yrs.
- Inorganic NO₃ tablets consisted of nitrate-rich beetroot extract, thiamin nitrate, and potassium nitrate in the presence of ascorbic acid, to facilitate NO formation

DEMOGRAPHICS

	Placebo n= 35	Active n= 32
Age, yrs. (mean +/- SD)	60.9 ± 8.5	57.5 ± 9.4
Female, n (%)	23(65.7)	18(56.3)
Ethnicity		
Caucasian, n (%)	5 (14.29)	6 (18.75)
African-American, n (%)	5 (14.29)	5 (15.63)
Hispanic, n (%)	19 (54.29)	17 (53.13)
Asian, n (%)	6 (17.14)	4 (12.5)
Body Mass Index, (kg/m ²)	32.24 ± 6.56	33.63 ± 9.21

RESULTS

Table 1. BP reduction stratified by placebo and active treatment

Group		Baseline vs. 2weeks	P value *	Baseline vs. 12weeks BP reduction	P value*
Placebo	SBP	2.7 ± 10.2	0.12	6.19 ± 11.39	0.004
	DBP	0.53 ± 10.4	0.76	1.98 ± 9.38	0.241
Active	SBP	3.6 ± 14.3	0.18	12.5 ± 13.3	0.0007
	DBP	-0.2 ± 11.1	0.82	4.7 ± 10.3	0.0179

* data present by mean ± SD and P value comes from paired t test.

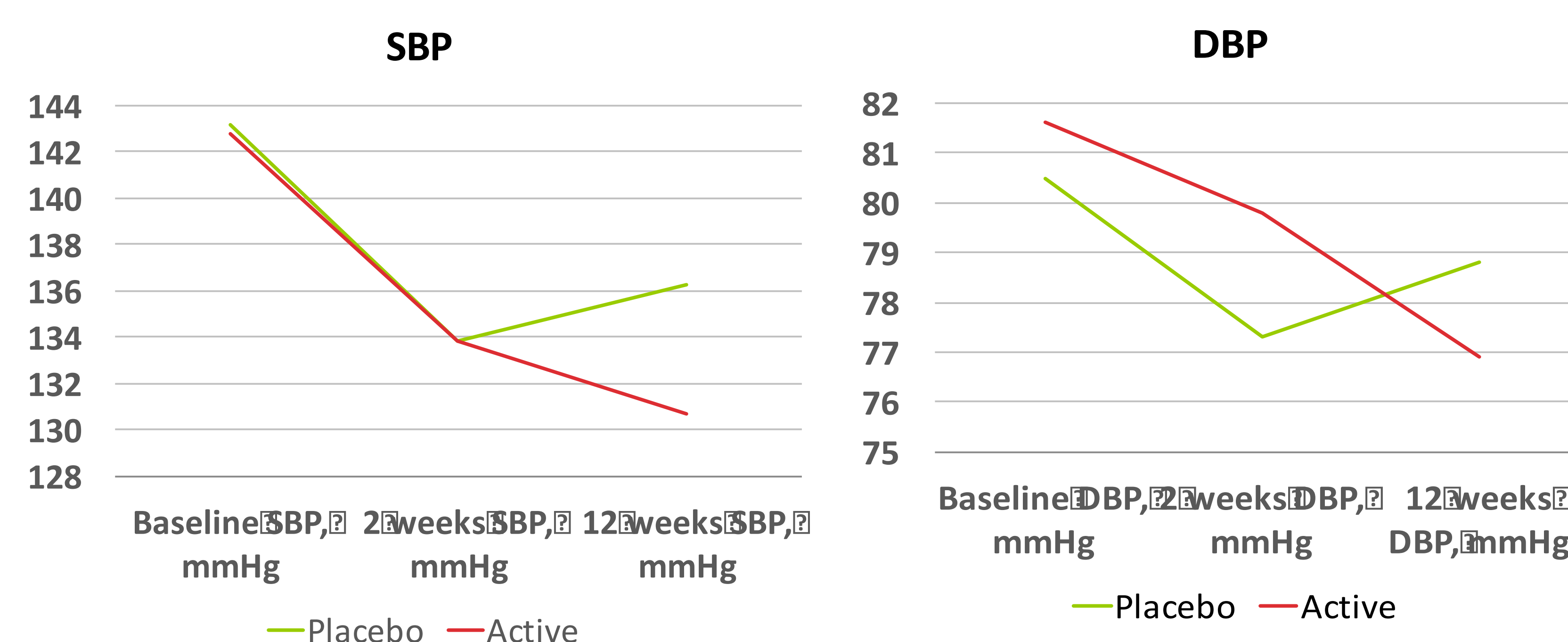


Chart 1. Mean SBP and DBP in between two groups at each study visit

Table 2. Brachial Flow Mediated Dilation (bFMD)

Group	Baseline (BL)	2 hours (2hr)	12 weeks (12wk)	Within Group Mean Change BL to 12wk	P value
Placebo (n= 32)	3.0 ± 1.9	3.3 ± 2.1	3.1 ± 1.8	0.1 ± 1.8	0.82
Active (n= 30)	2.9 ± 2.0	4.0 ± 2.4	3.7 ± 4.2	0.8 ± 3.1	0.03

*Compared to Baseline, reported in % (5 patients excluded because of poor image quality of bFMD)

CONCLUSION

- Both systolic and diastolic BP were robustly reduced in pre-hypertensive individuals with daily supplementation of inorganic dietary NO₃.
- Inorganic NO₃ supplementation {Berkeley life} has the potential to be used to complement anti-hypertensive therapies, including plant-based dietary approaches, for BP control.

DISCUSSION

- Hypertension is the most common risk factor for global disease burden and is estimated to cause 10 million cardiovascular deaths per year.
- Endogenous NO has therapeutic effects on hypertension and various cardiovascular risk factors.
- NO is a potent vasodilator and also protects the vessel wall against the development of atherosclerosis and thrombosis by inhibiting platelet aggregation, smooth muscle cell migration and proliferation, monocyte adhesion and adhesion molecule expression.
- Green leafy vegetables are a great dietary source for this NO₃⁻. (after absorption NO₃⁻ is converted to NO₂⁻ and then bioactive NO)
- Plant based bioequivalent inorganic NO₃⁻ supplement {Berkeley Life, Chicago, IL} has the potential to be used to complement anti-hypertensive therapies, including plant-based dietary approaches, for BP control.
- Such observations highlight the importance and growing need for accessible and effective anti-hypertensive interventions.

REFERENCES

1. Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380:2224-60
2. Endothelium-derived Relaxing Factors of Small Resistance Arteries in Hypertension. *Toxicol Res*. 2014;30(3):141-

DISCLOSURES

- Matthew J. Budoff, M.D., FACC - Research/ Research Grants: General Electric; Berkeley Life, Chicago, IL.
- All other authors have no conflicts of interest