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| **Control Number:** | 793 |
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| **Abstract Title:** | Effects of *Nitrosomonas Eutropha* D23 Topical Spray on Blood Pressure: Results From a Randomized, Double-blind, Vehicle Controlled, Dose-ranging Study in Normotensive Adults |
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| **Abstract Body:** | Objective: To evaluate the safety and blood pressure effects in normotensive individuals of *Nitrosomonas eutropha* bacteria applied as a topical spray. Methods: After initial screening, 36 healthy, normotensive adults participating in a facial acne vulgaris treatment trial were randomized to placebo or one of three concentrations (2, 4, or 8 x$10^9$ cells/ml) of a pure culture of ammonia oxidizing bacteria strain *N. eutropha* D23. Treatment occurred through the application of a topical spray to the face, which delivered ~0.6ml twice daily for 14 days. A standardized safety assessment (including physical exam and 12-lead EKG) and an evaluation of systolic and diastolic blood pressure occurred on Days 1 (pre-treatment), 3, 7, 10, 15 and on Day 28 |

following a 14 day wash-out. Results: A total of 9 subjects in each treatment group were randomized and completed the study (8 men and 28 women). Pre-treatment blood pressure was similar across treatment groups (115-119/75-79 mmHg). A dose-dependent reduction in systolic and diastolic blood pressure was emergent by treatment day 3. At day 15, individuals treated with the 8 x$10^9$ cells/ml concentration experienced a reduction in systolic blood pressure of 6.1 mmHg from baseline (SD=5.9; p=0.014) and diastolic blood pressure was reduced by 3.56 mmHg from baseline (SD=4.49; p=0.041). By comparison, in the placebo group, the treatment phase systolic and diastolic blood pressure changes from baseline were -0.34 (SD=7.80; p=0.94) and -1.19 (SD=4.57; p=0.486) respectively. Blood pressure reductions observed at Day 15 with *N. eutropha* were generally maintained at Day 28. All 3 concentrations of *N. eutropha* and placebo (vehicle alone) were well tolerated and no safety issues were identified. Conclusions: Topical treatment with the ammonia oxidizing bacteria *N. eutropha D23* produced a dose-dependent reduction in systolic and diastolic blood pressure that was statistically significant in the 8 x$10^9$ cells/ml treatment group. This effect is consistent with the proposed mechanism-of-action of *N. eutropha* treatment: modification of $NO/NO_2$ levels on the skin. These findings support further development of *N. eutropha* for treatment of acne vulgaris and evaluation of blood pressure lowering effects in hypertensive individuals.

**Category:** Clinical Trials in Hypertension and Related Morbidities

**Presentation Preference:** Poster Only

**Award Application:** I do not wish to be considered for an award

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