

## **Statistical analysis plan and sample size calculation**

### **Official Title:**

The Effect of Chronic Nitrate Supplementation on Acute Mountain Sickness and Exercise Performance in Hypoxia

### **NCT number**

NCT03101904

### **Document Date**

15/10/2015

## High-altitude headache

### RM ANOVA

2x4 RM ANOVA = Total of 8 repeated measures

	Av correlation		Meaningful difference	Effect size		Sample size
	Calculated	Table		Calculated	Table	
Hypoxia	0.6	Strong = 0.5	14	0.7	Large = 0.57	14
			10	0.5	Medium = 0.35	23
All data	0.2	Weak = 0.3	14	0.7	Large = 0.49	16
			10	0.5	Large = 0.49	16
4 measures	0.4	Weak = 0.3	10	0.7	Large = 0.49	16

### Calculations (4 measures)

#### Average correlation

		Hypoxic			Normoxic
		4 h	6 h	8 h	8 h
Hypoxic	4 h	1	0.4	0.4	
	6 h		1	0.9	
	8 h			1	-0.3
Normoxic	8 h				1

Average correlation = 0.4

#### Effect size

Meaningful difference = 10

SD of difference (4-6 h in hypoxia) = 18

Cohen's D = 0.55

Conversion to RM ANOVA effect size =  $0.55 / (\text{SQRT}(1-0.4)) = 0.7$

(Stevens, 2002)

A sample size estimation for this analysis indicated that 16 participants were needed to produce an 80% chance of obtaining statistical significance at the 0.05 level (5), based on a minimum important difference of 10 mm (2), a standard deviation of the difference of 18 mm, and an estimated average correlation of 0.4 (data from (3)).

## Time to exhaustion

**t tests** – Means: Difference between two dependent means (matched pairs)

<b>Analysis:</b>	A priori: Compute required sample size		
<b>Input:</b>	Tail(s)	=	Two
	Effect size dz	=	0.9090909
	$\alpha$ err prob	=	0.05
	Power (1- $\beta$ err prob)	=	0.8
<b>Output:</b>	Noncentrality parameter $\delta$	=	3.1491833
	Critical t	=	2.2009852
	Df	=	11
	Total sample size	=	12
	Actual power	=	0.8174086

The effect of nitrate supplementation on maximal exercise performance (TTE) was determined by paired samples t-test. A sample size estimation for this analysis indicated that 12 participants were needed to produce an 80% chance of obtaining statistical significance at the 0.05 level for a two-tailed design (1), based on a minimum important difference of 30 seconds and a standard deviation of the difference of 33 seconds (data from (4)). Given the smaller required sample size for this analysis, only 15 participants completed the TTE component of the study.

## References

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